

User Guide

OSMOMAT 3000



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Original Device Documentation
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! This manual allows for the safe and efficient operation of the OSMOMAT 3000 (hereafter "device"). This manual is part of the device and must be stored in the immediate vicinity of the device and be easily accessible to personnel at any time.

Personnel must carefully read and understand this manual before beginning any kind of work. Compliance with the safety notices and instructions in this manual is the basis for a safe work environment. In addition, local accident prevention regulations and general safety provisions for the intended use of the device must be followed.

Figures in this manual are included for basic understanding and may differ from the actual application.

Other applicable documents

In addition to this manual, the documents included with the device documentation apply. The warnings— in particular safety notices — in this documentation must be observed!

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The contents of this manual are protected by copyright. Their use is permitted in connection with the use of this device. Any use beyond this scope is not permitted without prior written authorization from Gonotec GmbH.

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DOMINIQUE DUTSCHER SAS

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DOMINIQUE DUTSCHER SAS

1 Overview of the OSMOMAT 3000

This device is an in-vitro diagnostic product which measures the osmolality of a sample. For details about the measuring method, see ↗ page 26.



Fig. 1: Device overview—front

- 1 Touchscreen, ↗ page 30
- 2 Upper cooling system (behind movable elevator cover), ↗ page 28
- 3 Thermistor probe with measuring vessel, ↗ page 29
- 4 Lower cooling system, ↗ page 29
- 5 Elevator
- 6 Printer (Option D), ↗ page 32

Device, rear

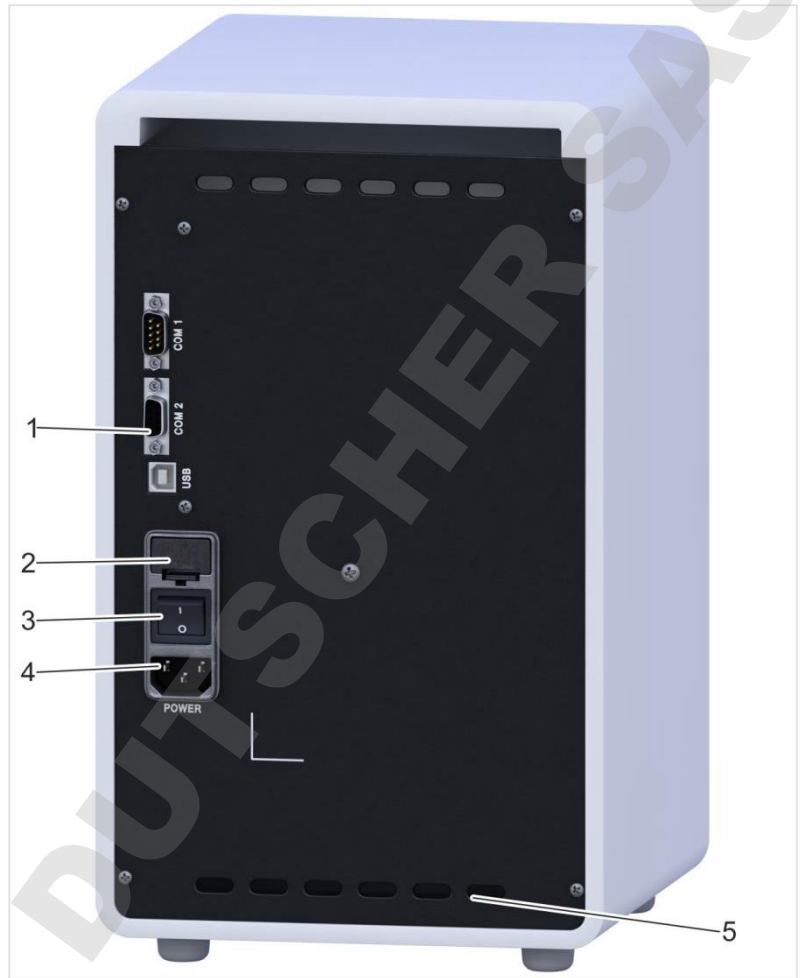


Fig. 2: Device overview—rear

- 1 Interfaces, ↗ page 33
- 2 Fine-wire fuses
- 3 On/Off switch
- 4 Power cord connection
- 5 Fan outlet

Consumables



NOTE!

Risk of falsified measurement results!

When using accessories and/or consumables made by manufacturers other than Gonotec GmbH, the reproducibility of the measurement results cannot be guaranteed.

- Always use the accessories and consumables supplied by Gonotec GmbH.
- Order used-up consumables, in particular measuring vessels, from Gonotec GmbH (see page 2 for contact information).



- 1 Measuring vessels, 100 pc.
- 2 Calibration standard, 10 pc., 1ml each, concentration 300 mOsmol/kg
- 3 Printer paper, 1 roll (Option D only)

Fig. 3: Overview of consumables

Accessories



Fig. 4: Overview of accessories

- | | | | |
|---|--|---|---|
| 1 | Power cord | 5 | 2 fine-wire fuses, 1 A |
| 2 | RS-232 cable | 6 | Ampoule opener |
| 3 | USB cable for connection to PC (slave) | 7 | Blow-out device for removing condensate (Pasteur pipette) |
| 4 | Adjustment tool | | |

2 Safety

2.1 Explanation of symbols

Safety notices

The safety notices in this manual are identified by symbols. The safety notices are preceded by signal words indicating the degree of hazard.

**DANGER!**

This combination of symbol and signal word indicates an immediate dangerous situation that will result in death or serious injury if not avoided.

**WARNING!**

This combination of symbol and signal word indicates a potentially dangerous situation that may result in death or serious injury if not avoided.

**CAUTION!**

This combination of symbol and signal word indicates a potentially dangerous situation that may result in minor or light injury if not avoided.

**NOTE!**

This combination of symbol and signal word indicates a potentially dangerous situation that may result in property damage if not avoided.

**NOTE!**

This combination of symbol and signal word indicates potential environmental hazards.

Special safety notices

Safety notices use the following symbols to indicate special hazards:


DANGER!

This combination of symbol and signal word indicates an immediate dangerous situation due to electrical current. Failure to observe a warning identified this way will result in serious or deadly injury.

Safety notices in instructions

Safety notices can apply to specific, individual instructions. These safety notices are embedded in the instruction to avoid interrupting the flow of reading while performing the operation. They use the signal words described above.

Example:

1. Loosen screw.

- 2.


CAUTION!





Pinch hazard on cover!

Use care when closing cover.

3. Tighten screw.

Additional identifiers

To highlight instructions, results, lists, references, and other elements, the following identifiers are used in this manual:

Identification	Explanation
 1, 2, 3 ...	Step-by-step instructions
	Results of action steps
	References to sections in this manual and other applicable documents
	Unordered lists
[Button]	Controls (such as buttons or switches), display elements (such as indicator lamps)
"Display"	Screen elements (such as buttons, function key assignments)

Safety

2.2 Intended use

Intended use

The OSMOMAT 3000 device is a non-invasive in-vitro diagnostic product used to determine the osmolality of aqueous solutions.

- Only use the device to measure aqueous solutions.
- Never measure organic, saturated, or highly viscous solutions.
- Never administer measured samples to humans by infusion or injection.
- Never use calibration standards as cleaning solutions, e.g. for contact lenses.
- Only use accessories and consumables supplied by Gonotec GmbH for measurements.

🔗 *Accessories and consumables on page 24*

2.3 Additional hazards

2.3.1 Hazards due to electrical current

Electrical current



DANGER!

Risk of death due to electrical current on device!

Class I devices must be connected to a power socket with protective ground wire.

If the power or device connector is used as a separation device, the connector must be easily accessible at all times.

Remove the power plug from the power socket to safely disconnect the device from mains voltage.

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately disconnect the power plug and schedule a repair.
- Always route the power cord so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

2.3.2 Risk of infection

Risk of infection

**WARNING!**

Risk of infection due to sample residue and in case of inadequate hygiene, disinfectant cleaning, and sterilization procedures!

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfectant cleaning, and sterilization.

We recommend using detergents such as Mikrozyd® AF Liquid, Bacillol® plus 3%, or Korsolex® plus 4% commonly found in clinical-chemical labs to clean and decontaminate the device.

2.3.3 Risk of injury

Risk of injury

**CAUTION!**

Risk of injury from initiation needle!

When installing and removing the initiation needle and the thermistor probe, the tip of the initiation needle is exposed. Movement of the initiation needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the initiation needle.

Safety

2.3.4 Risks of device damage

Exposure to liquids and moisture

**NOTE!****Device damage due to exposure to liquids and moisture!**

Exposure to liquids and moisture can cause damage to the electrical components of the device, e.g. due to a short.

- Install the device on a dry workplace.
- Always use a moistened wipe to disinfect the device, but never a wet wipe.
- Never use the device outdoors.

Fan

**NOTE!****Device damage due to insufficient air circulation!**

Obstruction of the fan outlet at the rear of the device can cause damage to the device.

- Always keep the fan outlet clear.

Shock

**NOTE!****Risk of property damage due to exposure of the device to strong shock!**

The device includes precision-engineered components which can be decalibrated and/or damaged in case of exposure of the device to strong shock.

- Always install the device on a non-vibrating surface.

ESD

**NOTE!****Risk of property damage due to ESD of the device!**

Electrostatic discharge (ESD) can occur when working on the open device.

- Take ESD precautions.

2.3.5 Reproducibility of the measurement

Incorrect measuring vessels

**NOTE!****Risk of non-reproducibility of measurement due to incorrect measuring vessels!**

Repeated use of the measuring vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measuring vessel for every measurement.
- Only use measuring vessels supplied by Gonotec GmbH.
- Never use centrifugal measuring vessels.

Improper handling of the calibration standard

**NOTE!****Risk of non-reproducibility of measurement due to improper handling of calibration standards!**

Improper handling and storage of the calibration standards included with the delivery negatively affects the measurement accuracy of the device.

- Always observe the stability of the calibration standards after opening the ampoule (0.5h at 22°C ambient temperature).
- Never use opened ampoules twice or mix them together.
- Never freeze opened ampoules.
- Do not use the calibration standards past their expiration date.

Shock

**NOTE!****Increased risk of incorrect measurements!**

The device includes precision-engineered components which can be decalibrated and/or damaged in case of exposure of the device to strong shock. This can cause a higher risk of incorrect measurements (spontaneous crystallization).

- Always install the device on a non-vibrating surface.

2.4 Operator responsibilities

The operator of the device must fulfill the responsibilities according to Germany's Medical Devices Operator Ordinance listed in this manual.



In addition, the operator is responsible for learning about and complying with all local laws and associated standards and guidelines applicable at the time the device is used.

The device is used for medical-pharmaceutical applications. Therefore, the operator is subject to the legal responsibilities regarding work safety.

In particular, the following applies:

- The operator has to learn about the applicable work safety regulations and determine additional risks resulting from the specific working conditions at the location the device is used by means of a risk assessment. These must be implemented by means of operating instructions for the device.
- The operator has to learn about the applicable hygiene regulations resulting from the samples at the location the device is used. These must be implemented by means of operating instructions for the device.
- During the entire operating time of the device, the operator has to verify that the operating instructions created by him/her meet the current body of regulations and update them if necessary.
- The operator has to determine and lay down the specific responsibilities for installation, operation, troubleshooting, servicing, disinfection, and cleaning.
- The operator has to make sure that all personnel working with the device have read and understood this manual. In addition, s/he has to provide regular training for personnel and educate them about risks.
- The operator has to equip personnel with the required safety gear and issue mandatory instructions for wearing the required safety gear.
- The operator has to make sure that the service intervals specified in this manual are observed.
- The operator has to make sure that consumables are available in sufficient quantities.

Inventory

The operator has to maintain an inventory according to Germany's Medical Devices Operator Ordinance:

- The following information has to be maintained in the inventory:
 - name, product type, serial number, and year the device was purchased,
 - address of Gonotec GmbH
 - organization-specific ID, if applicable
 - location of operator
 - schedule of safety inspections
- Store CE-certificate together with inventory.
- Store inventory so it is accessible to personnel in charge of operating the device at all times.
- Make documentation available to the responsible authority upon demand.

2.5 Personnel requirements

**WARNING!****Risk of injury due to inadequately qualified personnel!**

Work performed on the device by unqualified personnel or the presence of unqualified personnel in the hazard zone of the device creates risks that can result in serious injury and substantial property damage.

- Only have qualified personnel perform any kind of activity.

This manual specifies the following personnel qualifications for the different task areas:

User

Based on his or her expert medical and/or pharmaceutical training, knowledge, and experience, the user is capable of safely executing the tasks assigned to him or her.

The user is not authorized to perform any start-up activities.

The user is capable of independently detecting, evaluating, and avoiding possible risks.

The user has the expert knowledge for the intended use of the device and observes all hygiene regulations for rooms used for medical purposes and the use of medical products.

The user knows the contents of all applicable regulations, guidelines, and standards required by law for the safe use of the device and is capable of meeting the requirements stipulated therein.

Lab supervisor

The lab supervisor coordinates and monitors the technical procedures at the installation site of the device.

Based on his or her professional training and many years of professional experience with medical devices, the lab supervisor is capable of performing the start-up tasks delegated to him or her by the manufacturer.

Service technician

Based on his or her professional training in the area of mechanical and electrical engineering, the service technician is capable of performing the tasks related to troubleshooting and servicing delegated to him or her by the manufacturer.

2.6 Personal safety gear

While performing the different tasks on and with the device, personnel must wear the personal safety gear referenced explicitly in the various sections of this manual.

Description of personal safety gear The personal safety gear is explained below:



Disposable lab gloves

Disposable lab gloves protect the hands from touching sample residue.

2.7 Environmental protection



NOTE!

Danger to environment due to incorrect handling of handling of environmentally hazardous substances!

Incorrect handling of environmentally hazardous substances, in particular incorrect disposal, can result in significant harm to the environment.

- Always observe the warnings regarding the handling of environmentally hazardous substances and their disposal below.
- If environmentally hazardous substances are inadvertently released into the environment, immediately initiate suitable actions. If in doubt, notify the responsible local authority about the damage and inquire about suitable actions to be initiated.
- If environmentally hazardous substances are inadvertently released into the environment, immediately initiate suitable actions. If in doubt, notify the responsible authority about the damage and inquire about suitable actions to be initiated.

The following environmentally hazardous substances are used:

Electronic components

Electrical components can contain poisonous substances. These must not be released into the environment. Therefore, a specialist disposal firm must be tasked with disposal.

Sodium chloride

The calibration standards contain sodium chloride. Sodium chloride is mildly hazardous to water and must not be released into the environment.

3 Design and function

3.1 Device overview

This device is an in-vitro diagnostic product which measures the osmolality of a sample. For details about the measuring method, see [page 26](#).



Fig. 5: Device overview—front

- 1 Touchscreen, [page 30](#)
- 2 Upper cooling system (behind movable elevator cover), [page 28](#)
- 3 Thermistor probe with measuring vessel, [page 29](#)
- 4 Lower cooling system, [page 29](#)
- 5 Elevator
- 6 Printer (Option D), [page 32](#)

Device, rear

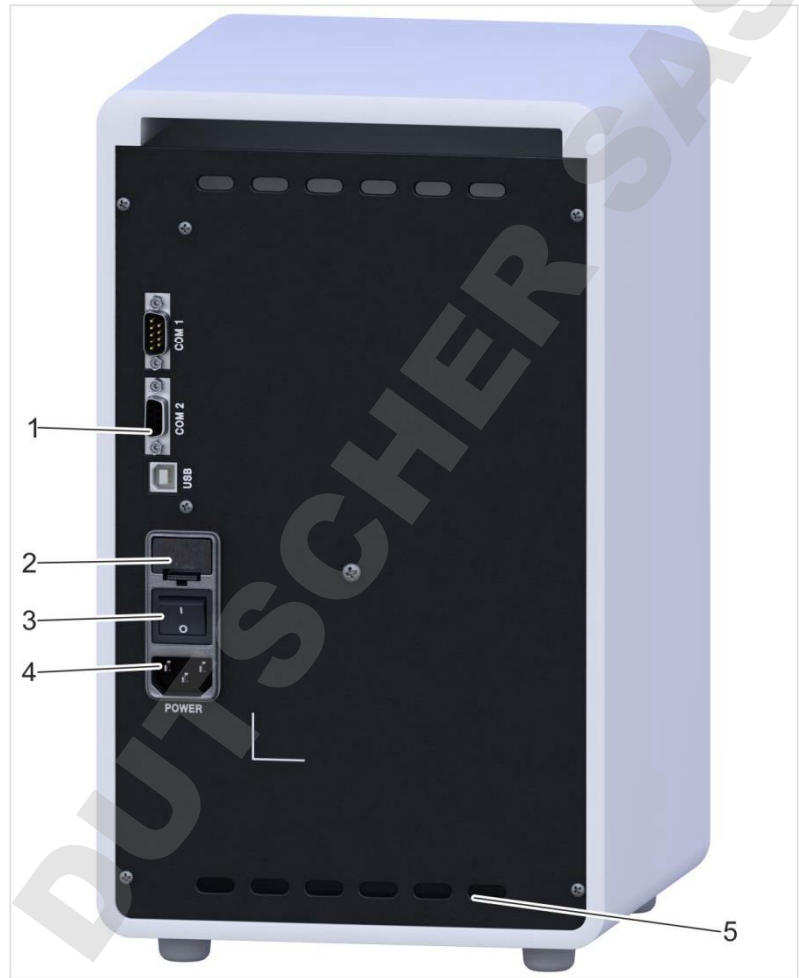


Fig. 6: Device overview—rear

- 1 Interfaces, ↗ page 33
- 2 Fine-wire fuses
- 3 On/Off switch
- 4 Power cord connection
- 5 Fan outlet

Consumables

**NOTE!****Risk of falsified measurement results!**

When using accessories and/or consumables made by manufacturers other than Gonotec GmbH, the reproducibility of the measurement results cannot be guaranteed.

- Always use the accessories and consumables supplied by Gonotec GmbH.
- Re-order consumables, in particular measuring vessels, from Gonotec GmbH (see page 2 for contact information).



- 1 Measuring vessels, 100 pc.
- 2 Calibration standard, 10 pc., 1ml each, concentration 300 mOsmol/kg
- 3 Printer paper, 1 roll

Fig. 7: Overview of consumables

Accessories


Fig. 8: Overview of accessories

- | | | | |
|---|--|---|---|
| 1 | Power cord | 5 | 2 fine-wire fuses, 1 A |
| 2 | RS-232 cable | 6 | Ampoule opener |
| 3 | USB cable for printer connection (slave) | 7 | Blow-out device for removing condensate (Pasteur pipette) |
| 4 | Adjustment tool | | |

Design and function

3.2 Measuring method basics

Osmolality

The device measures the total osmolality of any aqueous solution.

The total osmolality indicates the concentration of all osmotically active substances (such as salts, dextrose, proteins) per kilogram of water.

The osmolality is specified in mOsmol/kg.

The device determines the total osmolality of the sample solution based on the freezing point depression. The implemented measuring method is a relative measuring method.

The freezing points of distilled water and an aqueous solution are measured and compared. The osmolality of any solution is determined using a linear function defined by 2- or 3-point calibration.

Freezing point depression

The freezing point of a solution is depressed by adding soluble or mixable substances.

The freezing points of pure water and a solution are measured and compared. Whereas water has a freezing point of 0°C, a solution with a saline concentration of 1 osmol/kg has a freezing point of -1.858°C.

That means that one mol of a given non-dissociated substance (6.023×10^{23} parts diluted in one kilogram of water) lowers the freezing point of a solution by 1.858°C.

The following definitions are used in calculating osmolality:

$C_{\text{osm}} = \Delta T / K$	C_{osm} = osmolality [osmol/kg]
	T = freezing point depression [°C]
	K = 1.858°C kg/osmol freezing point constant

3.3 Measurement equipment



Fig. 9: Overview of measurement equipment

- | | |
|--|------------------------|
| 1 Elevator | 5 Lower cooling system |
| 2 Upper cooling system (behind movable elevator cover) | 6 Measuring vessel |
| 3 Handle for lowering the thermistor probe | 7 Cover |
| 4 Thermistor probe | |

The sample is pipetted into the measuring vessel (fig. 9/7). The measuring vessel is placed on the thermistor probe (fig. 9/4) and lowered into the lower cooling system (fig. 9/5). The lower cooling system cools the sample down to a defined temperature.

The defined crystallization of the sample is triggered using ice crystals produced in the upper cooling system (fig. 9/2).

Based on the freezing point [°C] and the freezing point constant, the device determines the osmolality of the sample. The value is shown on the touchscreen.



NOTE!

Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

Upper cooling system

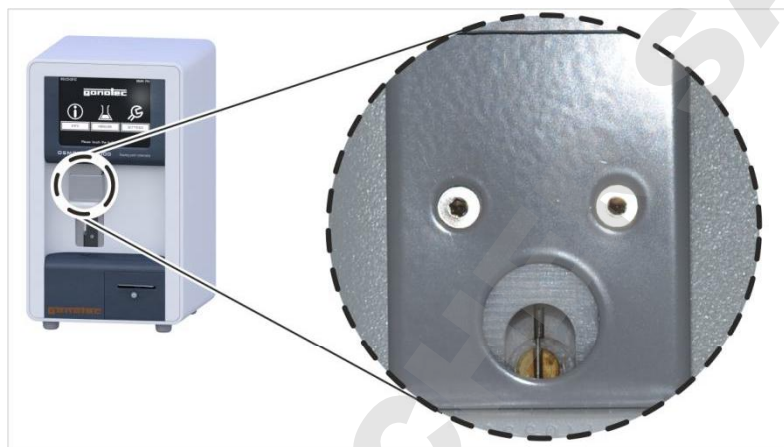


Fig. 10: Upper cooling system

- 1 Initiation needle
- 2 Cooling nipple

The initiation needle (fig. 10/1) of the upper cooling system "inoculates" the sample with ice crystals ("crystallization"). This causes the sample to freeze and heat up to its freezing point.

**WARNING!****Risk of infection from sample residue!**

The initiation needle is immersed into the sample during measurements. Contact with the initiation needle increases the risk of infection.

- Wear lab gloves during any kind of work.

Thermistor probe

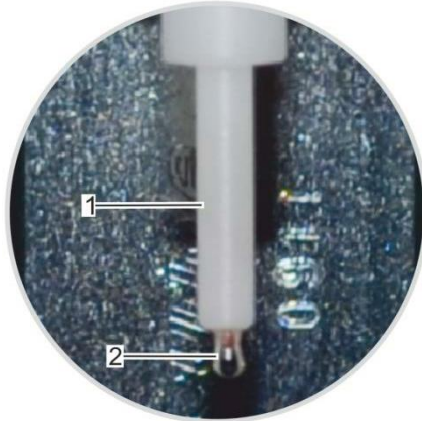


Fig. 11: Thermistor probe

- 1 Thermistor probe
- 2 Thermistor

The thermistor probe (fig. 11/1) measures the current temperature of the sample via the thermistor (fig. 11/2). After crystallization has been triggered, the thermistor probe measures the freezing point of the sample.



NOTE!

Sensitive component!

The thermistor of the thermistor probe is a sensitive component and must be protected from external influences such as dust or friction.

- When performing any kind of work on the device, place a measuring vessel on the thermistor probe.
- At the end of the work on the device, place a measuring vessel on the thermistor probe for protection.

Lower cooling system

The lower cooling system quickly cools the sample down to a defined temperature. This temperature is below the freezing point. The quick cooling down of the sample causes the sample to remain in the liquid state until the defined crystallization is triggered.

3.4 Touchscreen



Fig. 12: Overview of touchscreen

The device is controlled using the touchscreen (fig. 12/1)



NOTE!

Property damage due to incorrect operation!

The touchscreen can be damaged by sharp or hard objects or excessive pressure force.

- Only operate the touchscreen using fingers or a touch pen.
- Only tap the touchscreen (do not press).

Enter values



Some menus are password-protected.
Access to these menus is limited to the lab supervisor or authorized service personnel/Gonotec.

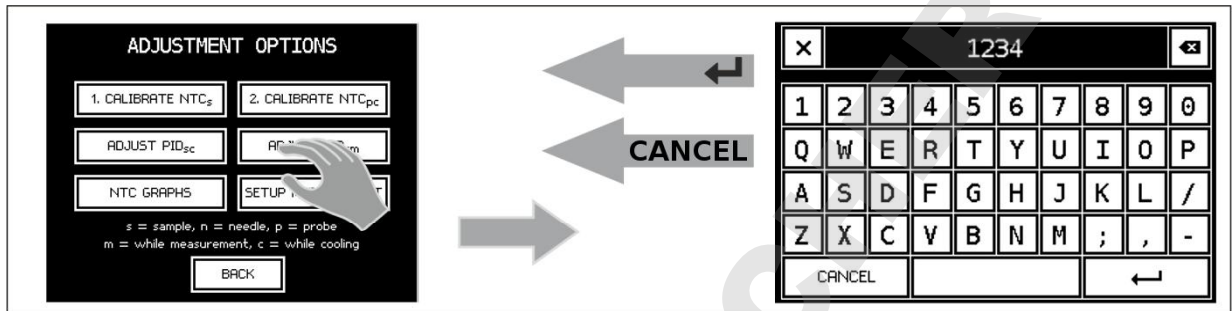


Fig. 13: Enter values

1. To enter values, tap the corresponding entry field in the opened menu.
⇒ This opens an on-screen keyboard.
2. Enter the value.



To close the on-screen keyboard without saving the entered value, tap [Cancel].

3. To save the value, tap .
⇒ The newly entered value overwrites the previous value.

Design and function**3.5 Printer**

With built-in printer (only Option D)

- 1 Opening for printer paper
- 2 Printer pull-out handle

The printer is used to print the measurement results. Rolls of printer paper are included with the delivery.

**Change printer paper**

Change the printer paper when a red stripe appears on the printer paper (↪ chapter 8.4.5 "Replace printer paper (Option D only)" on page 84).

Fig. 14: Overview of printer

3.6 Connections and interfaces

The following connections and interfaces are located at the rear of the device:



Fig. 15: Connections and interfaces

- | | | | |
|---|---|---|-----------------------|
| 1 | COM1 - only for connecting the barcode reader (Option BC) | 4 | Fuse insert |
| 2 | COM2 interface (RS-232 output) | 5 | On/Off switch |
| 3 | USB connector | 6 | Power plug connection |

Design and function

3.6.1 Interface configuration

COM1 data port

The upper COM1 (RS232) serial data port is used to connect a barcode reader. The barcode reader is configured at the factory and can be purchased from Gonotec GmbH or your authorized distributor.



WARNING!

Incompatible barcode reader!

The use of a barcode reader other than the barcode reader supplied by Gonotec GmbH is not recommended because potential incompatibilities cannot be ruled out.



WARNING!

To protect life and equipment:

Devices and accessories connected to the RS232 or USB connectors must meet the applicable safety standards for medical lab equipment.

COM2 or USB data port



Fig. 16: Set protocol port

The device can output the recorded measurement results via the COM2 (RS232) serial data port in the middle or the USB port.

To select the data port, select **Log Port** from the **Settings** menu item. The following screen lets you select between **COM2** and **USB**.

USB port driver

A software driver is required to use the USB port.

There are two methods for installing the driver:

- **Automatic:** Connect the device to the PC using the USB cable and switch on the device. The operating system of the PC detects the interface, automatically installs the required software driver and notifies the user that installation was successful. The USB port can now be used as an additional COM interface.
- **Manual:** The PC does not automatically detect the device or the operating system is missing the required software driver. In this case, please follow the instructions on the included CD. It includes both the installation instructions for the corresponding Windows operating system and the software driver itself.

3.6.2 Transfer protocol

Output format:	ASCII The comma sign (ASCII 0x2C ",") to separate data columns and the carriage return sign (ASCII 0x0d <CR>) sign to separate lines.															
Baud rate:	Transmission speed: 9600 bps.															
Data format:	8 data bits no parity 1 stop bit is sent.															
Contents of data output:	<p>Prior to every data output, the system places a header at the beginning of a charge and in front of every sample measured individually:</p> <p><i>charge, sample, date, time, value, device, device-no<CR></i></p> <p>The output below follows every successful measurement:</p> <p><i><charge>,<sample>,<date>,<time>,<value>,<device>,<device-no><CR></i></p> <p><charge> The charge number (alphanumeric) or a minus sign "-" if no charge is running.</p> <p><sample> The sample number (alphanumeric).</p> <p><date> The date of the measurement in German notation "mm/dd/yyyy".</p> <table border="0" style="margin-left: 20px;"> <tr> <td>mm</td> <td>month, two-digit</td> <td>[01..12]</td> </tr> <tr> <td>dd</td> <td>day, two-digit</td> <td>[1..31]</td> </tr> <tr> <td>yyyy</td> <td>year, four-digit</td> <td>[2010]</td> </tr> </table> <p><time> The time of the measurement in German notation "HH:MM".</p> <table border="0" style="margin-left: 20px;"> <tr> <td>HH</td> <td>hour</td> <td>[00..23]</td> </tr> <tr> <td>MM</td> <td>minute</td> <td>[00..59]</td> </tr> </table> <p><value> The measurement value without decimal places (in mmol/l).</p> <p><device> Alphanumeric device name (such as "OSMOMAT 3000").</p> <p><deviceno> The device number (alphanumeric).</p>	mm	month, two-digit	[01..12]	dd	day, two-digit	[1..31]	yyyy	year, four-digit	[2010]	HH	hour	[00..23]	MM	minute	[00..59]
mm	month, two-digit	[01..12]														
dd	day, two-digit	[1..31]														
yyyy	year, four-digit	[2010]														
HH	hour	[00..23]														
MM	minute	[00..59]														

4 Delivery, packaging, and storage

Delivery condition



1 package containing the following components:

- Device with protective sleeve (fig. 17/1)
- Accessories (fig. 17/2–8):
 - Blow-out device (Pasteur pipette) (fig. 17/3)
 - Adjustment tool (fig. 17/8)
 - 1 package of 2 1A fine-wire fuses (fig. 17/6)
 - Ampoule opener (fig. 17/4)
 - USB cable (fig. 17/5)
 - RS232 cable (fig. 17/7)
 - Power cord (fig. 17/2)
- Consumables (fig. 17/9-11)
 - Printer paper (fig. 17/9) (Option D only)
 - Measuring vessels, 100 pc. (fig. 17/10)
 - Calibration standard 300mOsmol/kg, 1 package of 10 ampoules/1ml each (fig. 17/11)
- 1 user guide



Check the delivery for completeness and transport damage immediately following receipt.

Proceed as follows in case of externally visible transport damage:

- Reject delivery or accept delivery only conditionally.
- Note the extent of damage on the transport documents or the delivery note of the carrier.
- Notify Gonotec GmbH and initiate a complaint.



File a complaint about every defect as soon as it is detected. Claims for damages can only be filed within applicable complaint deadlines.

Fig. 17: Delivery condition

4.1 Packaging

About the packaging

The package is packaged according to the expected transport conditions. Only environmentally friendly materials were used for the packaging.

The packaging is intended to protect the device from transport damage and other damage until the time of installation. Therefore, do not destroy the packaging and do not remove it until just before installation.

Handling of packaging materials

The packaging is multi-use and ensures a hygienic and safe method of transportation. Keep the packaging for possible return of the device for repairs. This will save you the time and money needed to find equally suitable packaging.

If disposing of the packaging material, observe the following:



NOTE!

Danger to environment due to improper disposal!

Packaging materials are valuable resources and can be re-used or recycled in many cases. Improper disposal of packaging materials can cause dangers to the environment.

- Be aware of the environment when disposing of the packaging material.
- Observe applicable local disposal regulations. If necessary, task a specialist firm with disposal.

Symbols on packaging

The symbols on the packaging of the device and calibration standard are explained below:

Fragile



Indicates packages with fragile or sensitive contents.

Handle the package with care, do not drop, and do not expose to shock.

Protect from liquid



Protect packages from liquid and keep dry.

Delivery, packaging, and storage

Package orientation



The arrow tips of the symbol point to the top of the package. They must point up at all times to prevent damage to the contents.

No disposal via municipal waste



Indicates that disposal of the device via municipal waste is prohibited. Disposal of the decommissioned device should be via electronics and metal recycling. In addition, decommissioned devices can be returned to the manufacturer for disposal.

Package recycling



Indicates that the packaging can be recycled.

Conformity



This product meets the requirements of EEC Directive 98/79 relating to in-vitro diagnostics.

In vitro diagnostic product



In-vitro diagnostic product.

Item number



Item number

Batch ID



Batch ID of the calibration standard

Expiration date



Expiration date (month, year). Date until which the calibration standard fulfills its original function if stored properly.

4.2 Device storage

Store the device under the following conditions:

- Do not store outside.
- Store under dry and dust-free conditions.
- Do not expose to aggressive media.
- Protect from sunlight.
- Protect the thermistor probe using a measuring vessel.
- Avoid mechanical shock.
- Storage temperature: -10°C to 60°C.
- Relative humidity (non-condensing): 5-90%.
- If stored for more than 3 months, regularly inspect all parts and packaging for general integrity.

4.3 Unpack device

1. Carefully open cardboard box using a knife.
2. Remove device from packaging and place in a suitable location.
3. Keep packaging for possible later return.

5 Installation

5.1 Transport device inside lab

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Position a measuring vessel (fig. 18/1) on the thermistor probe.



Fig. 18: Position measuring vessel



The measuring vessel is securely attached to the thermistor probe when it clicks into place.



Fig. 19: Position transport safety device

3. Tilt transport safety device for thermistor probe and carefully slide behind the thermistor probe (fig. 19).



Fig. 20: Device with protective sleeve

4. Pull protective sleeve (fig. 20/1) included with the delivery over device.
5. Lift up device (6.5kg) and carry to installation site.

5.2 Install device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves



Fig. 21: Fan outlet (1)

1.



NOTE!
Risk of property damage!
 Only install device indoors.

Install device at installation site.



NOTE!
Risk of incorrect measurements

Select site based on the following criteria:

- free of vibrations
- no direct heat exposure (sun, electric heater, etc.)
- no strong air flows
- free of dust and dirt

Keep fan outlet (fig. 21/1) clear.

Keep fan outlet openings underneath device clear.



Fig. 22: Remove protective sleeve

2. Remove protective sleeve from device (fig. 22/1).



Fig. 23: Transport safety device

3. Remove transport safety device (fig. 23/1) from thermistor probe. Proceed as follows:



Fig. 24: Remove transport safety device

4. Carefully pull transport safety device down and pull forward to remove.

5.3 Connect device

Personnel: ■ Lab supervisor

1. Connect power plug to device.
2. Connect power cord to a properly grounded power socket.
3. Connect a PC via RS232 or USB (if applicable).
4. Connect a barcode reader (option, if applicable).

6 Setup

Personnel: ■ Lab supervisor

1. Complete all activities for installation and connection of the device.
2. Verify that the connections at the rear side of the device are secure.
3. Check the elevator for ease of movement.

If necessary, grease the elevator guide (↪ *chapter 9.3 "Lubricate elevator" on page 94*).

4. Power up device on rear side using on/off switch.

Check printer (Option D)

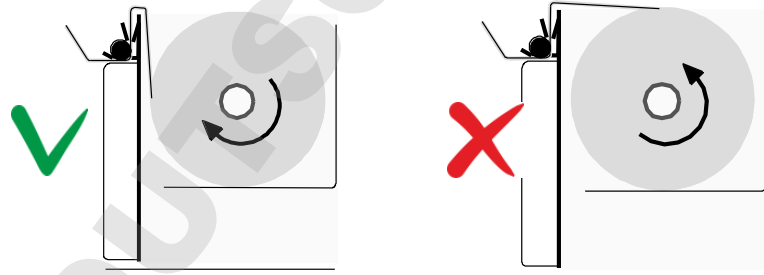


Fig. 25: Paper roll feed direction

- ✓ Correct feed direction
- ✗ Incorrect feed direction

5. Check feed direction of paper roll. Open the printer and compare the feed direction of the paper roll with the feed direction shown in fig. 25.

Check free movement of initiation needle

6. Check initiation needle for free movement.
Open the "Adjust Needle" menu (*Start menu* → *Settings* → *Lab Options* → *Adjust Needle*).

Setup



Fig. 26: "Adjust Needle" menu

7.



CAUTION!

Risk of injury from initiation needle!

The tip of the initiation needle is exposed. Movement of the initiation needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the initiation needle.

Tap "Move Needle" and ensure that the initiation needle moves freely.

Tap "Quit" to complete the check.

Set calibration procedure

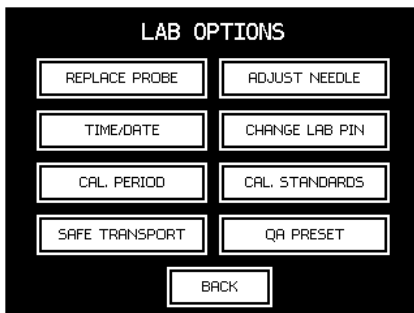


Fig. 27: "Lab Options" menu

8. Open the menu for configuring the lab options.

In the Start menu, tap *Settings* → *Lab Options*.



The menu can be protected with a lab supervisor password.

To configure the calibration interval, tap "Cal.-Period".

To select the calibration standards you are using, tap "Cal.-Standards".

To set up the calibration method, tap "QA Preset".

Configure calibration interval



Fig. 28: Configure calibration interval

9. Select a calibration interval.

When selecting "Manual," the device does not prompt you for calibration (not recommended).

Select calibration standards



Fig. 29: Select calibration standards

10. Specify the allowed calibration points (Unit mOsmol/kg). They should be close to the expected measurement values.

Set up calibration method

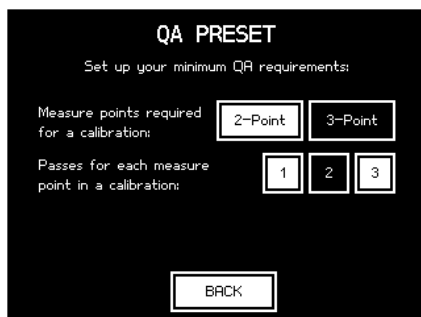


Fig. 30: Set up calibration method

11. Select the calibration method:

- "2-Point": Select 2-point calibration
- "3-Point": Select 3-point calibration

12. Select the number of measurements to be performed for each calibration medium (distilled water and calibration standard).

The system calculates the calibration points from the mean value of these measurements.



The number of measurements for each calibration point does not affect the linearity or reproducibility of the measurement system. They are only used to arrive at the mean value.

7 Operation

Electrical current

**DANGER!****Risk of death due to electrical current on device!**

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately disconnect the power plug and schedule a repair.
- Always route the power cord so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Ensure easy access to the power socket at all times.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

Risk of infection

**WARNING!****Risk of infection due to sample residue and in case of inadequate hygiene, disinfectant cleaning, and sterilization procedures!**

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfectant cleaning, and sterilization.

7.1 Power up device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves



Fig. 31: Power up device

1. Power up device on rear side using on/off switch (fig. 31/1).

7.2 Measure individual samples

- Personnel: ■ User
- Safety gear: ■ Disposable lab gloves
- Materials: ■ Soft paper towel
■ Pipette
■ Measuring vessel
■ Sample

**NOTE!****Risk of non-reproducibility of measurement due to incorrect measuring vessels!**

Repeated use of the measuring vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measuring vessel for every measurement.
- Only use measuring vessels supplied by Gonotec GmbH.
- Never use centrifugal measuring vessels.

**NOTE!****Risk of incorrect measurement resulting from the presence of air bubbles in the sample!**

- The sample must be pipetted **without** air bubbles.



Fig. 32: Clean thermistor probe

1. Clean thermistor probe (fig. 32/1) using a soft paper towel.



Fig. 33: Start menu

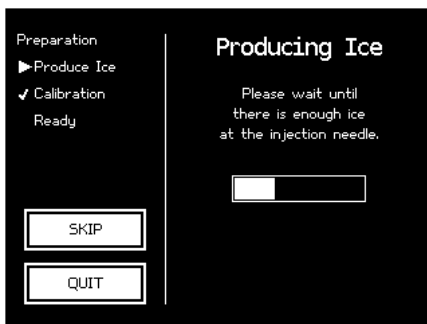


Fig. 34: Ice formation

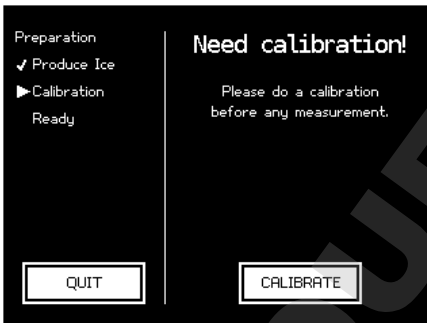


Fig. 35: Calibrate device

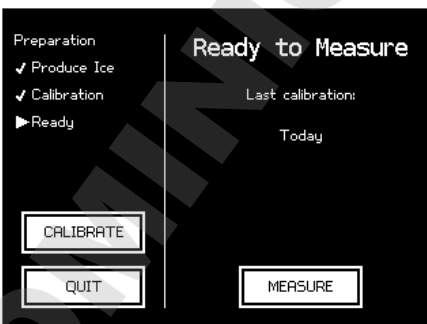


Fig. 36: Device is ready for measurement

2. Tap "Measure" on the Start menu (Fig. 33).

⇒ If the operating time of the device is less than 3 minutes, the menu for ice formation is displayed.

3. Wait until ice forms on the initiation needle (Fig. 34).

⇒ After successful ice formation, the menu for calibration or the measurement menu is displayed (depending on the configured calibration interval).

4. If necessary, calibrate device (Fig. 35).

⇒ [chapter 7.4 "Calibrate device" on page 56](#)



Calibration cannot be canceled.

The calibration interval is defined by the lab supervisor.

⇒ The device is ready.

5. Tap "Measure" (Fig. 36).

⇒ The measurement menu opens.

Operation



Fig. 37: Pipette sample

6. Pipette a sample volume of 50µl into an unused and clean measuring vessel (Fig. 37).



NOTE!

Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.



Fig. 38: Position measuring vessel

7. Position measuring vessel on thermistor probe with cover facing front (Fig. 38/1).



The measuring vessel is securely attached to the thermistor probe when it clicks into place.

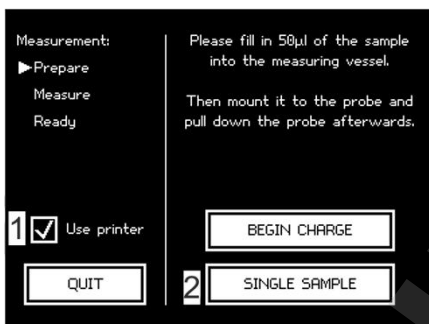


Fig. 39: Measurement menu

8. Option D only:

Tap "Printer On" on the measurement menu (Fig. 39/1) to output the measurement results to a printer. Make sure that the printer is ready.

9. To start the measurement, tap "Single Sample" (Fig. 39/2).

If necessary, enter the sample ID using the virtual keyboard.



The sample ID can be pre-defined in the user preferences. In this case, the system assigns the sample ID automatically (🔗 page 63)



Fig. 40: Move elevator down

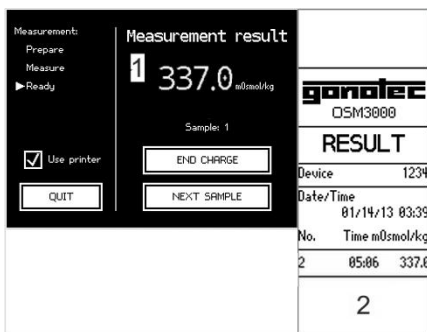


Fig. 41: Measurement result

10. Move elevator (Fig. 40/1) down.



Moving the elevator up during the measurement will abort the measurement.

⇒ The sample measurement is performed automatically. Pay attention to the displays on the touchscreen.

The measurement result displays on the touchscreen (Fig. 41/1) and, if applicable, prints (Fig. 41/2) (Option D).



Reproducibility:

$\leq \pm 2$ digits in the measurement range [0..400] mOsmol/kg

$\leq \pm 0.5\%$ in the measurement range [400..1500] mOsmol/kg

$\leq \pm 1.0\%$ starting with 1500 mOsmol/kg



Fig. 42: Clean thermistor probe

11. Move elevator up.



Moving the elevator up during the measurement will abort the measurement.

12. Remove measuring vessel from thermistor probe.

Dispose of measuring vessel and sample according to local regulations.

13. Clean thermistor probe (Fig. 42/1) using a soft paper towel.



NOTE!

Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.

Operation

7.3 Perform series measurement

- Personnel: ■ User
- Safety gear: ■ Disposable lab gloves
- Materials: ■ Soft paper towel
 ■ Pipette
 ■ Measuring vessel
 ■ Samples



NOTE!

Risk of non-reproducibility of measurement due to incorrect measuring vessels!

Repeated use of the measuring vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measuring vessel for every measurement.
- Only use measuring vessels supplied by Gonotec GmbH.
- Never use centrifugal measuring vessels.



NOTE!

Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.



Fig. 43: Clean thermistor probe

1. Clean thermistor probe (fig. 43/1) using a soft paper towel.



Fig. 44: Start menu

2. Tap "Measure" on the Start menu (Fig. 44).

⇒ If the operating time of the device is less than 3 minutes, the menu for ice formation is displayed.



Fig. 45: Ice formation

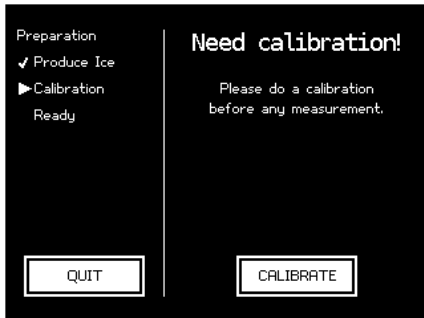


Fig. 46: Calibrate device

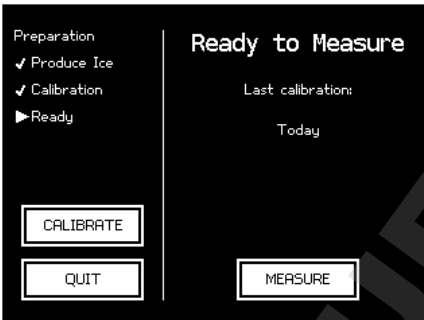


Fig. 47: Device is ready for measurement

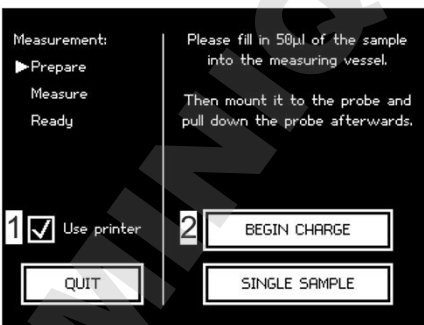


Fig. 48: Measurement menu

3. Wait until ice forms on the initiation needle (Fig. 45).
 - ⇒ After successful ice formation, the menu for device calibration or the measurement menu is displayed (depending on the configured calibration interval).

4. If necessary, calibrate device (Fig. 46).
 - ↳ chapter 7.4 "Calibrate device" on page 56

i Calibration cannot be canceled.
The calibration interval is defined by the lab supervisor.

⇒ The device is ready.

5. Tap "Measure" (Fig. 47).
 - ⇒ The measurement menu opens.

6. Option D only:
Tap "Printer On" on the measurement menu (Fig. 48/1) to output the measurement results to a printer.
Make sure that the printer is ready.
7. To start a series measurement, tap "Begin Charge" (Fig. 48/2).
8. Enter the charge ID.

i The charge ID can be pre-defined in the user preferences. In this case, the system assigns the charge ID automatically (↳ page 63)

Operation



Fig. 49: Pipette sample

9. Pipette a sample volume of 50µl into an unused and clean measuring vessel (Fig. 49).



NOTE!

Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.



Fig. 50: Position measuring vessel

10. Position measuring vessel on thermistor probe with cover facing front (Fig. 50/1).



The measuring vessel is securely attached to the thermistor probe when it clicks into place.



Fig. 51: Move elevator down

11. Move elevator (Fig. 51/1) down.



Moving the elevator up during the measurement will abort the measurement.

- ⇒ The sample measurement is performed automatically. Pay attention to the displays on the touchscreen.

The touchscreen shows the measurement result for the current sample.

- ⇒ Option D:

The measurement result prints.



Reproducibility:

$\leq \pm 2$ digits in the measurement range [0..400] mOsmol/kg

$\leq \pm 0.5\%$ in the measurement range [400..1500] mOsmol/kg

$\leq \pm 1.0\%$ starting with 1500 mOsmol/kg



Fig. 52: Clean thermistor probe

12. Move elevator up.



Moving the elevator up during the measurement will abort the measurement.

13. Remove measuring vessel from thermistor probe.

Dispose of measuring vessel and sample according to local regulations.

14. Clean thermistor probe (Fig. 42/1) using a soft paper towel.



NOTE!
Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.

15. Start the measurement of the new sample by repeating the work steps starting with step 9.

To complete the series measurement, tap "End Charge".

⇒ Option D:

Completing the series measurement also completes the printing operation.

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7.4 Calibrate device

Calibration methods

Depending on the pre-defined calibration interval, the menu for calibrating the device opens automatically. The device is calibrated using one of the following calibration methods:

- 2-point calibration: Calibration using distilled water and a calibration standard or
- 3-point calibration: Calibration using distilled water and 2 calibration standards

2-point calibration means that the device is calibrated using distilled water (zero point calibration) and one calibration standard.

3-point calibration means that the device is calibrated using distilled water (zero point calibration) and 2 calibration standards.

The calibration method, the calibration standards used for calibration, and the calibration interval are defined by the lab supervisor during start-up (☞ *chapter 6 "Setup" on page 43*).

Calibrate device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Materials: ■ Soft paper towel
 ■ Pipette
 ■ Distilled Water
 ■ Calibration standard (e.g. 300 mOsmol/kg)
 ■ Ampoule opener
 ■ Measuring vessels



NOTE!

Risk of non-reproducibility of measurement due to incorrect measuring vessels!

Repeated use of the measuring vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measuring vessel for every measurement.
- Only use measuring vessels supplied by Gonotec GmbH.
- Never use centrifugal measuring vessels.



Fig. 53: Clean thermistor probe

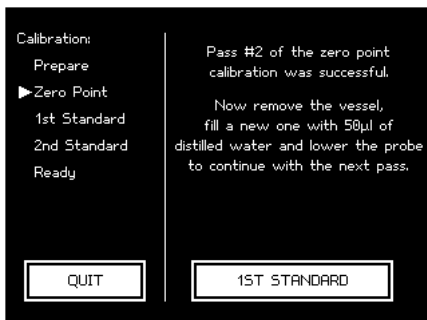


Fig. 54: Perform zero point calibration

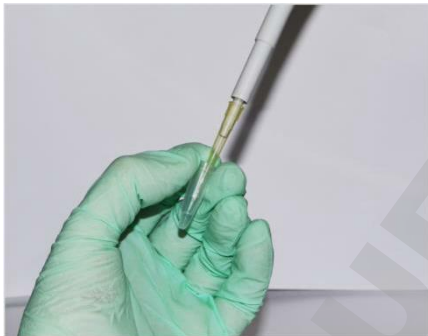


Fig. 55: Pipette distilled water



Fig. 56: Position measuring vessel

1. Clean thermistor probe (fig. 53/1) using a soft paper towel.

2. Follow the instructions on the touchscreen.

3. Pipette a distilled water volume of 50µl into an unused and clean measuring vessel (Fig. 55).

**NOTE!**

Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

4. Position measuring vessel on thermistor probe with cover facing front (Fig. 56/1).



The measuring vessel is securely attached to the thermistor probe when it clicks into place.

Operation

Perform zero point calibration



Fig. 57: Move elevator down

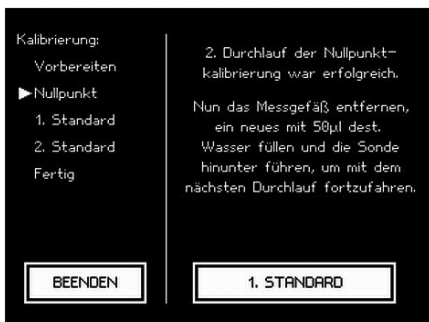


Fig. 58: Calibrate device using calibration standard

5. Move elevator (Fig. 57/1) down.
 - ⇒ Zero point calibration starts automatically.
 - Zero point calibration is performed automatically. Pay attention to the displays on the touchscreen.

6. Move elevator up.
7. Remove measuring vessel from thermistor probe.
 - Dispose of measuring vessel and sample according to local regulations.
8. Clean thermistor probe (Fig. 53/1) using a soft paper towel.



NOTE! Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.

9. Following successful zero point measurement, tap "1. Standard" to start calibration using the first calibration standard.



Successful calibration means that it was possible to measure the sample without errors.

This is not a plausibility check, which is not performed until the entire calibration sequence is completed in measurement mode (↪ page 97).

Calibrate device using calibration standard



NOTE!

Risk of non-reproducibility of measurement due to improper handling of calibration standards!

Improper handling and storage of the calibration standards included with the delivery negatively affects the measurement accuracy of the device.

- Always observe the stability of the calibration standards (0.5h at 22°C ambient temperature).
- Never use opened ampoules twice or mix them together.
- Never freeze opened ampoules.
- Do not use the calibration standards past their expiration date.

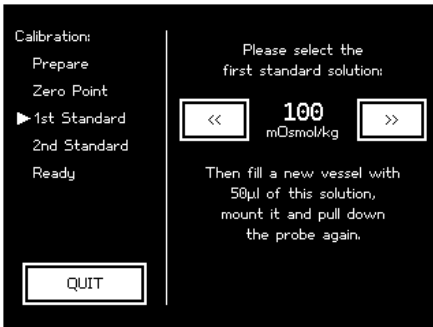


Fig. 59: Select calibration standard

10. Select the calibration standard using the "<<" and ">>" arrow keys.

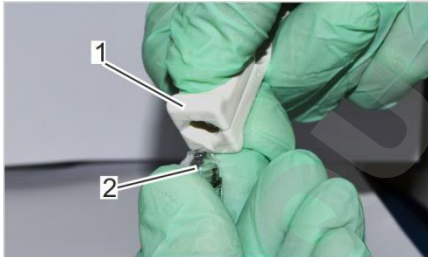


Fig. 60: Open ampoule

11.



WARNING!

Risk of injury at ampoule breaking points!

Use the ampoule opener (fig. 60/2) to open the ampoules containing the calibration standards (fig. 60/1).

Operation



Fig. 61: Pipette calibration standard

12. Pipette a calibration standard volume of 50µl into an unused measuring vessel (fig. 61).



NOTE!

Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

13. Position Measuring vessel on thermistor probe with cover facing front.



The measuring vessel is securely attached to the thermistor probe when it clicks into place.



Fig. 62: Move elevator down

14. Move elevator (Fig. 62/1) down.

⇒ Calibration starts automatically.

Calibration using the calibration standard is performed automatically. Pay attention to the displays on the touchscreen.

15. Move elevator up.

16. Remove measuring vessel from thermistor probe.

Dispose of measuring vessel and sample according to local regulations.

17. Clean thermistor probe (Fig. 62/1) using a soft paper towel.



NOTE!

Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.

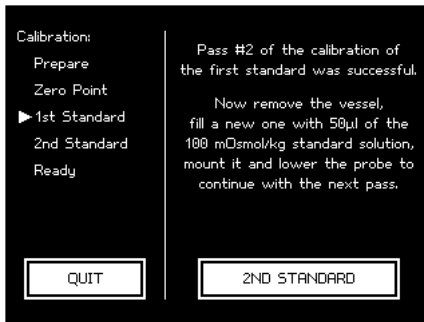


Fig. 63: Second calibration standard

For a 3-point calibration, repeat steps 9 through 17 using another calibration standard.

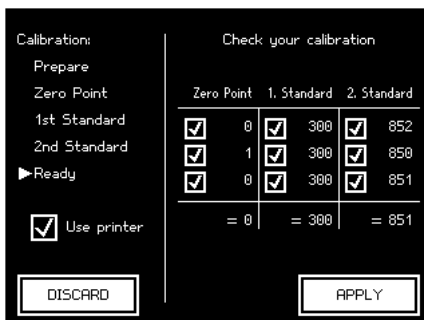


Fig. 64: Calibration results

The calibration results (Fig. 64) display following successful calibration of the device. The calculated osmolalities are mean values of the individual measurements.

This is the result of a 3-point calibration.

18. Verify the calibration results.

If necessary, tap the individual measurement values to ignore them during mean value calculation.



Reproducibility:

≤ +/- 2 digits in the measurement range [0..400] mOsmol/kg

≤ +/- 0.5% in the measurement range [400..1500] mOsmol/kg

≤ +/- 1.0% starting with 1500 mOsmol/kg

19. Tap "Apply" to complete the calibration.

⇒ The device is now calibrated.

20. Verify reproducibility (↻ page 97)

or continue with your measurements (↻ sample measurement on page 49, ↻ series measurement on page 53).

Operation

7.5 Modify user preferences

Overview

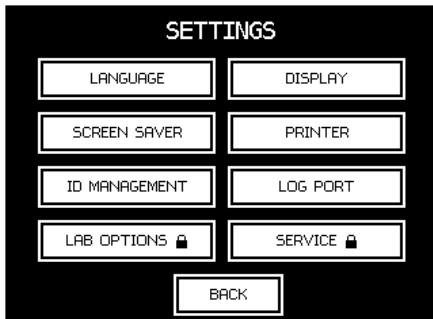


Fig. 65: Overview of user preferences

Tapping "Settings" on the Start menu opens the "Settings" menu. The "Settings" menu lets the user configure the following settings:

- "Language": Configure language
- "Display": Configure screen contrast
- "Screen Saver": Configure screen saver
- "Printer": Activate paper feed (Option D only)
- "ID Management": Configure ID for sample and series measurement
- "Log-Port": Configure interfaces for data transfer



The "Lab Options" option is protected with the lab supervisor password.

The "Service" option is protected with the service password. Modifications have to be requested by contacting the manufacturer.

Configure language



Fig. 66: Configure language

1. Tap "English".
⇒ The system language is English.
2. Tap "Deutsch".
⇒ The system language is German.

Configure screen contrast

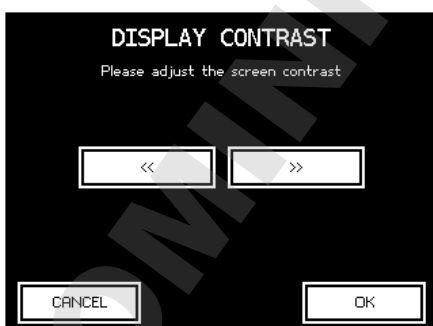


Fig. 67: Configure screen contrast

1. Tap ">>" to increase contrast.
Tap "<<" to decrease contrast.

Configure screen saver



Fig. 68: Configure screen saver

1. Select the duration after which the system activates the screen saver.
Tapping "OFF" will never activate the screen saver.

Activate paper feed



Fig. 69: Activate paper feed

1. Option D only:
Tap "Paper Feed".
⇒ The paper feed of the printer is activated briefly.
Tap "Quit" to exit the menu.

Configure sample ID



Fig. 70: Configure sample ID

1. Select the settings for the IDs for series measurements ("Charge ID") and individual samples ("Sample ID"). The following options are available:
 - automatic: The samples and the charge IDs are assigned running numbers automatically. The counter resets daily. The counter for the individual samples in a series measurement resets when starting a new series measurement.
 - numeric: Numeric IDs are assigned manually. During measurements, the system prompts the user to enter the numeric ID of the sample or charge using the virtual keyboard.
 - alphanumeric: Alphanumeric IDs are assigned manually. During measurements, the system prompts the user to enter the alphanumeric ID of the sample or charge using the virtual keyboard.

Operation

Set protocol port



1. Select the interface for data transfer to the PC.
To test the data transfer to the PC, press "Send Test String".

Fig. 71: Set protocol port

7.6 Power down device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves



Fig. 72: Power down device

1. Power down device using on/off switch on rear side (fig. 72/1) and disconnect power plug.



Fig. 73: Position measuring vessel

2. Position a measuring vessel (Fig. 73/1) on the thermistor probe.



The measuring vessel is securely attached to the thermistor probe when it clicks into place.



Fig. 74: Device with protective sleeve

3. Disinfect device if powered down for an extended period of time. Wipe device using a wipe moistened with disinfectant.
4. Pull protective sleeve (Fig. 74/1) included with the delivery over device.

8 Troubleshooting

8.1 Safety notices

Electrical current

**DANGER!****Risk of death due to electrical current on device!**

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately switch off the voltage supply and schedule a repair.
- Always route the power cord so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Ensure easy access to the power socket at all times.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

Risk of infection

**WARNING!****Risk of injury due to sample residue and in case of inadequate hygiene, disinfectant cleaning, and sterilization procedures!**

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfectant cleaning, and sterilization.

Risk of injury

**CAUTION!****Risk of injury from initiation needle!**

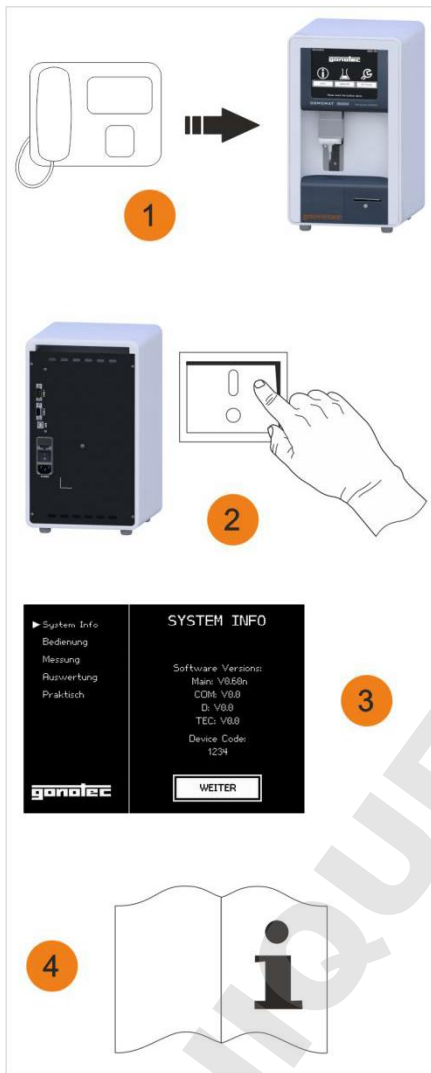
When installing and removing the initiation needle and the thermistor probe, the tip of the initiation needle is exposed. Movement of the initiation needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the initiation needle.

8.2 Notes regarding errors

In case of errors that cannot be resolved using the error table on [page 68](#), contact the manufacturer.

Please be prepared when contacting the manufacturer as follows:



- 1 Use a telephone located close to the device.
- 2 Power up device.



NOTE!

Danger in case of continuous acoustic alarm!

In case of continuous acoustic alarm, the electronics components of the device can be damaged.

- Power down device again.

- 3 Note down the serial number of the device. To find the serial number, select *Start menu* → *Info*.
- 4 Have the device documentation available.

Contact info:

Gonotec GmbH
 GSG-Hof Reuchlinstr.10-11
 D-10553 Berlin

Phone: (030) 7809 588-0
 Fax: (030) 7809 588-88
 E-mail: contact@gonotec.com
 Web: <http://www.gonotec.com>

Fig. 75: Contact Gonotec

Troubleshooting

8.3 Error table



Errors marked * are shown as an error message on the touchscreen.

Error description	Possible Cause	Remedy	Personnel
Elevator gets stuck or makes squeaking noises when lowered	Mechanical wear	Lubricate the elevator guide using silicone spray (↗ page 95)	User
	Blockage from foreign objects	Check openings and remove foreign objects	User
Lower cooling system does not cool sample	Mechanical wear	Clean cooling clamp (↗ page 84)	Service technician
	Fan is defective or obstructed	Check if fan is operational and replace if necessary (↗ service manual)	
	Peltier element is defective	Replace lower cooling system (↗ service manual)	
Gear motor of initiation needle turns without stopping or does not turn one full revolution	Light barrier on gear motor disk is defective	Replace light barrier (↗ service manual)	Service technician
	Light barrier on gear motor disk is misaligned	Adjust light barrier	
	Gear motor disk misaligned or loose	Adjust/tighten gear motor disk	
No or poor ice crystal formation in upper cooling system	Peltier element defective	Replace upper cooling system (↗ service manual)	Service technician
	Cable connection between cooling system and PCB defective		
	Cooling nipple dirty	Clean cooling nipple using a fiberglass pin (↗ page 96) Remove any droplets from opening using blow-out device.	User

	Error in rotation of gear motor disk (initiation needle drive)	Align initiation needle (☞ <i>page 73</i>)	Service technician
		Correct length of initiation needle (☞ <i>page 74</i>)	
		Check if light barrier is located properly and replace if necessary (☞ <i>service manual</i>)	
		Tighten gear motor disk	
	Ambient air too dry	Clean cooling nipple using a fiber-glass pin (☞ <i>page 96</i>)	User
Measurement procedure takes longer than usual	Fan is defective or obstructed	Check if fan is operational and remove any foreign objects Replace fan (☞ <i>service manual</i>)	Service technician
	Peltier element is defective	Replace lower cooling system (☞ <i>service manual</i>)	
Spontaneous crystallization *	Sample not prepared correctly	Use sample according to performance data of device (☞ <i>page 14</i>)	User
	Thermistor probe not aligned correctly	Align thermistor probe (☞ <i>page 80</i>)	Service technician
	Elevator moved up by user	Leave the elevator in the lowered position during the measurement procedure	User
Incorrect measurement results	Lower cooling system not aligned correctly	Align lower cooling system (☞ <i>service manual</i>)	Service technician
	Incorrect measuring vessel used	Only use measuring vessels of the correct type supplied by Gonotec GmbH	User
	Measuring vessel re-used	Use measuring vessels only once.	User
	Measuring vessel not positioned correctly	Position measuring vessel with cover pointing forward When the measuring vessel clicks into place, it is securely positioned on the thermistor probe.	User
		Thermistor probe defective	
	Thermistor probe not	Align thermistor probe (☞ <i>page 80</i>)	

Troubleshooting

	centered		
Measuring vessel fits too loosely on thermistor probe	Incorrect measuring vessel used Measuring vessel re-used	Only use measuring vessels supplied by Gonotec GmbH	User
	Measuring vessel not positioned correctly	Position measuring vessel with cover facing forward When the measuring vessel clicks into place, it is securely positioned on the thermistor probe.	User
	Thermistor probe damaged	Replace thermistor probe (☞ <i>page 76</i>)	Service technician
No crystallization * (see also: <i>No or poor ice crystal formation in upper cooling system</i>)	Initiation needle too long or too short	Adjust initiation needle to correct length (☞ <i>page 74</i>)	Service technician
	Initiation needle not deburred	Debur initiation needle using fine sandpaper	
	Initiation needle bent	Manually bend initiation needle so that it is vertical, replace if necessary (☞ <i>page 73</i>)	
	Initiation needle does not move Initiation needle disengaged from gear motor or stuck	Verify free movement of initiation needle (☞ <i>page 75</i>)	
Fan malfunction	Fan is obstructed	Check if fan is operational and remove any foreign objects	Service technician
	Fan is defective	Replace fan (☞ <i>service manual</i>)	
Fan makes loud noise	Fan is obstructed	Check if fan is operational and remove any foreign objects	
Continuous audible warning signal	Needle bar disengaged from gear motor or stuck	Verify free movement of initiation needle (☞ <i>page 75</i>)	Service technician
	Gear motor slider misaligned	<i>see also: Gear motor of initiation needle turns without stopping or does not turn one full revolution.</i>	
Fine-wire fuses trip when powering up device	Device voltage does not match power grid voltage	Check device voltage setting	Service technician

Device cannot be powered up	Power supply not correctly plugged into power socket	Connect power supply to a power socket	Service technician
	Power socket is dead	Connect device to a live power socket	
	Power cord is damaged	Replace power cord	
	Fuses are burned out	Replace fuses (↪ page 83)	
Printer does not print	Paper roll is used up	Replace paper roll (↪ page 84)	User
	Ribbon is empty	Replace ribbon (↪ page 86)	
Measurement procedure aborted by user*	User moved elevator up during measurement	Repeat measurement	User
Incorrect PIN entered*	Incorrect PIN entered	Re-enter PIN or cancel operation	Lab supervisor
Attempt to change lab supervisor password failed*	Repeat password entry does not match first entry	Change password again	Lab supervisor
Unexpected errors*	Internal system errors	Contact Gonotec GmbH	User

Troubleshooting

8.4 Resolve errors

8.4.1 Replace initiation needle

- Personnel: ■ Service technician
- Safety gear: ■ Disposable lab gloves
- Materials: ■ Allen key SW 2.5
■ Precision key file
■ Wire cutter



WARNING!

Risk of infection from sample residue!

The initiation needle is immersed into the sample during measurements. Contact with the initiation needle increases the risk of infection.

- Wear lab gloves during any kind of work.



DANGER!

Risk of death due to electrical current!

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Remove device front panel (↪ on page 89).

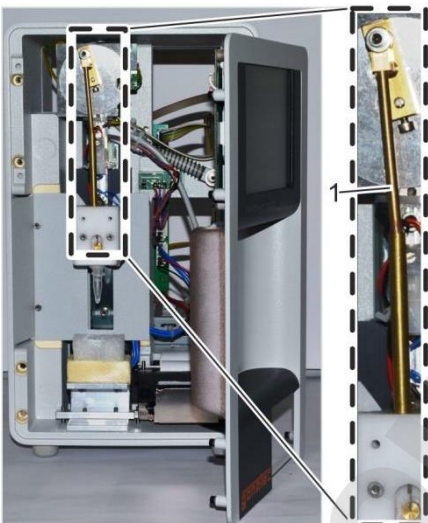


Fig. 76: Position of initiation needle and details

- 1 Initiation needle

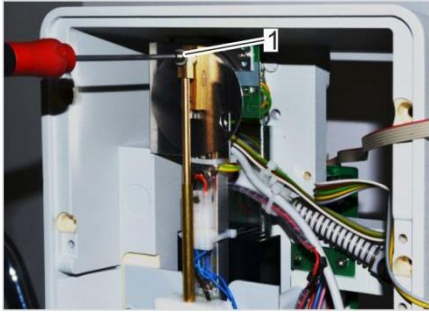


Fig. 77: Remove mounting screw

3. Remove mounting screw (fig. 77/1) of initiation needle while holding initiation needle in place.



The mounting screw has a coating of locking paint.



Fig. 78: Remove initiation needle

- 4.



Loose washer between initiation needle and gear motor disk!

Remove initiation needle from gear motor disk. Hold washer (fig. 78/1) of mounting screw in place.

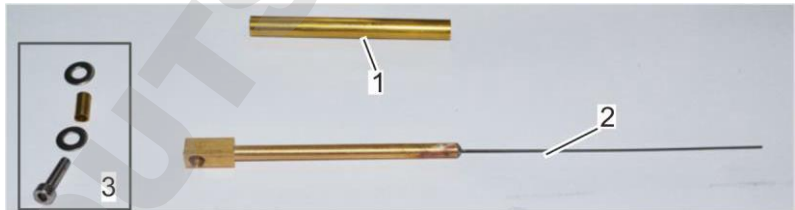


Fig. 79: Initiation needle components

5. Remove guide tube (fig. 79/1) and fasteners (fig. 79/3) of initiation needle (fig. 79/2).

6. Make sure that the new initiation needle is as straight as possible (fig. 80/1+2).

1 - Incorrect orientation

2 - Correct orientation

If necessary, bend initiation needle so it is straight (fig. 80/3).

7. Shorten initiation needle to correct length.

Proceed as follows.

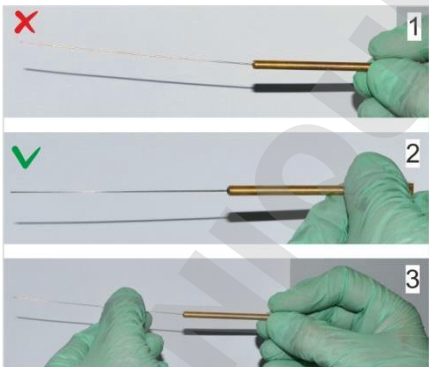


Fig. 80: Straighten initiation needle

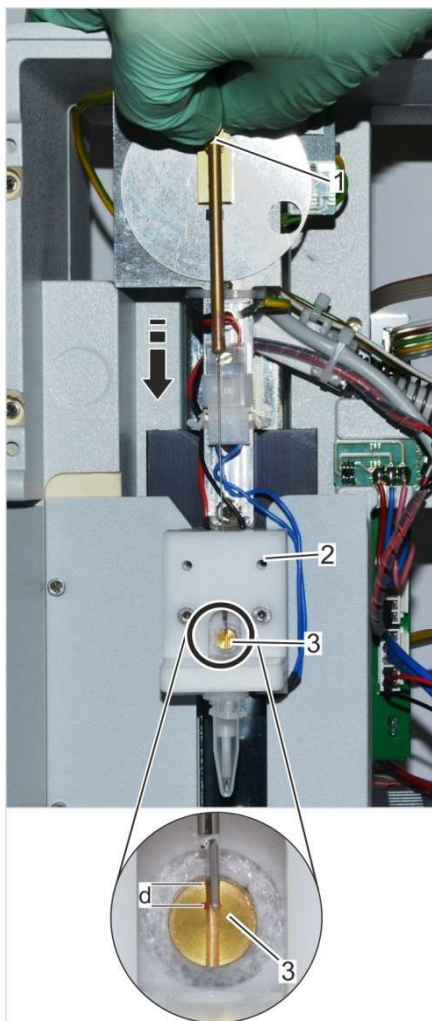


Fig. 81: Adjust length of initiation needle

8. Align gear motor swipe vertically with upper dead center (fig. 81/1).
⇒ The set screw of the gear motor swipe points down.
9. Move initiation needle through guide tube in upper cooling system (fig. 81/2) onto cooling nipple (fig. 81/3).
10. Bolt new initiation needle to gear motor disk.
11. Align initiation needle with gear motor swipe and cooling nipple. The needle end should be located approx. 2mm below the lower edge of the cooling nipple (d=2mm). (Fig. 81/3).
12. If the needle is too long, use a permanent marker to mark the correct length and remove the needle bar again.
13. Trim excess wire using side cutters and debur needle tip using precision key file.



Fig. 82: Install initiation needle

- | | | | |
|---|----------------|---|-------------------|
| 1 | Mounting screw | 4 | Initiation needle |
| 2 | Washer | 5 | Washer |
| 3 | Fastening tube | 6 | Guide tube |

14. Fit initiation needle to gear motor disk. Assemble fasteners as follows:
 - 1 - Push washer (fig. 82/2) and fastening tube (/3) onto mounting screw (fig. 82/1).
 - 2 - Push mounting screw with washer and fastening screw through head of initiation needle (fig. 82/4).
 - 3 - Secure washer (fig. 82/5) to mounting screw.
 - 4 - Push guide tube (fig. 82/6) onto initiation needle.
15. Secure initiation needle to gear motor disk (fig. 77) using mounting screw (fig. 82/1).

Check free movement of initiation needle



Fig. 83: Check free movement of initiation needle

16. Turn gear motor disk with attached initiation needle clockwise to check initiation needle for free movement.
If needle gets jammed, detach needle and check if it is bent. (Fig. Fig. 80).
17. Install device front panel (☞ on page 93).
18. Power up device on rear side using on/off switch.
19. Verify free movement of initiation needle automatically.
Open the menu for adjusting the initiation needle (*Settings* → *Lab Options* → *Adjust Needle*).



CAUTION!
Risk of injury from initiation needle!

The tip of the initiation needle is exposed. Movement of the initiation needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the initiation needle.

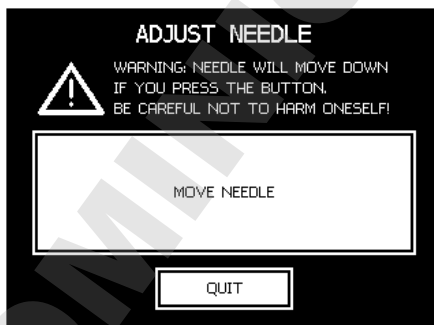


Fig. 84: Move needle

20. Tap "Move Needle" to test the free movement.
The initiation needle turns by one revolution.
Tap "Quit" to exit the menu.

8.4.2 Replace the thermistor probe

- Personnel: ■ Service technician
- Safety gear: ■ Disposable lab gloves
- Materials: ■ Allen key SW 2
■ Adjustment tool
■ Tweezers



WARNING!

Risk of injury in case of inadequate hygiene, disinfectant cleaning, and sterilization procedures!

Contact with the thermistor probe and initiation needle increases the risk of infection due to sample residue.

- Wear lab gloves during any kind of work.



DANGER!

Risk of death due to electrical current!

1. Power down device using on/off switch on rear side and disconnect power plug.
2. To protect thermistor, cover thermistor probe with a measuring vessel. The cover of the measuring vessel must point forward.

Remove elevator cover



Fig. 85: Position measuring vessel



NOTE!

Risk of thermistor damage due to loose position of measuring vessel!

Resistance is felt when sliding on measuring vessel. When the measuring vessel clicks into place, it is securely positioned on the thermistor probe.



Fig. 86: Move elevator down

3. Move elevator down using handle (fig. 86/1).



Fig. 87: Move elevator cover up

4. Move elevator cover (fig. 87/1) up.



Fig. 88: Remove mounting screws

5. Remove the 2 mounting screws (fig. 88/2) using Allen key (SW 2).



Fig. 89: Remove elevator cover

6. Remove the complete elevator cover (fig. 89/1).



Fig. 90: Pull connector

7. Pull connector of thermistor probe (fig. 90/1).



Fig. 91: Remove mounting screws

8. Move elevator up and remove the 2 mounting screws (fig. 91/1) using Allen key (SW 2).



Fig. 92: Remove thermistor probe

9. Remove thermistor probe with mounting plate toward the front (fig. 92) while holding guide tube of initiation needle (fig. 92/1) in place.

10. If necessary, clean cooling nipple.

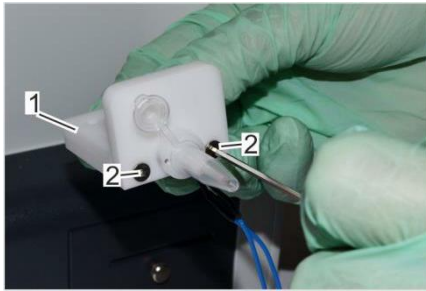


Fig. 93: Remove mounting plate

- 1 Mounting plate
- 2 Mounting screws

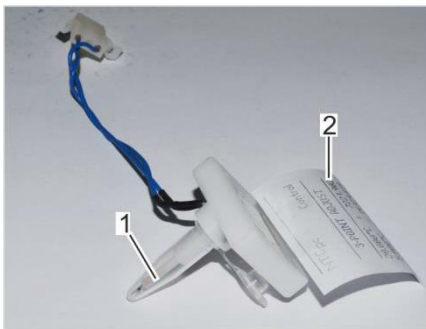


Fig. 94: New thermistor probe with data sheet

11. Use Allen key (SW 2) to remove thermistor probe from mounting plate (fig. 93).

12. Fit new thermistor probe to mounting plate (fig. 93).

Keep the data sheet affixed to the thermistor probe (fig. 94/2) in the vicinity of the device.

To protect thermistor, cover thermistor probe with a measuring vessel (fig. 94/1). The cover of the measuring vessel must point forward.



NOTE!

Risk of thermistor damage due to loose position of measuring vessel!

Resistance is felt when sliding on measuring vessel.

When the measuring vessel clicks into place, it is securely positioned on the thermistor probe.

13. Push guide tube onto initiation needle and pass needle through stainless steel tube of mounting plate (fig. 92).

Align the thermistor probe

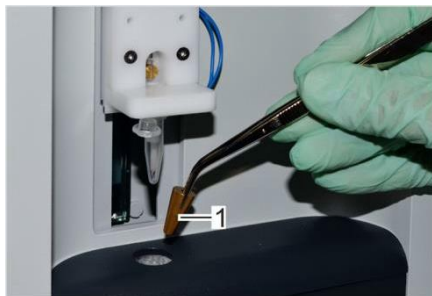


Fig. 95: Install adjustment tool

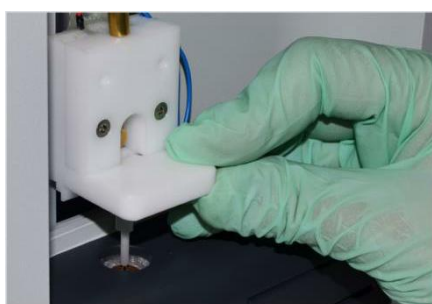


Fig. 96: Align the thermistor probe

14. Tighten the 2 mounting screws only lightly.
The thermistor probe must be aligned using the adjustment tool.
15. Install adjustment tool (Fig. 95/1) in opening of lower cooling system using tweezers.
16. Remove measuring vessel from thermistor probe.
17. Align thermistor probe (Fig. 96). Proceed as follows:
Push thermistor probe **just beyond** adjustment tool.
18. Position thermistor probe on its XYZ axis so that thermistor is perpendicular to center of hole of adjustment tool (Fig. 97 / Fig. 98).
19. Tighten the 2 mounting screws on the aligned thermistor probe.

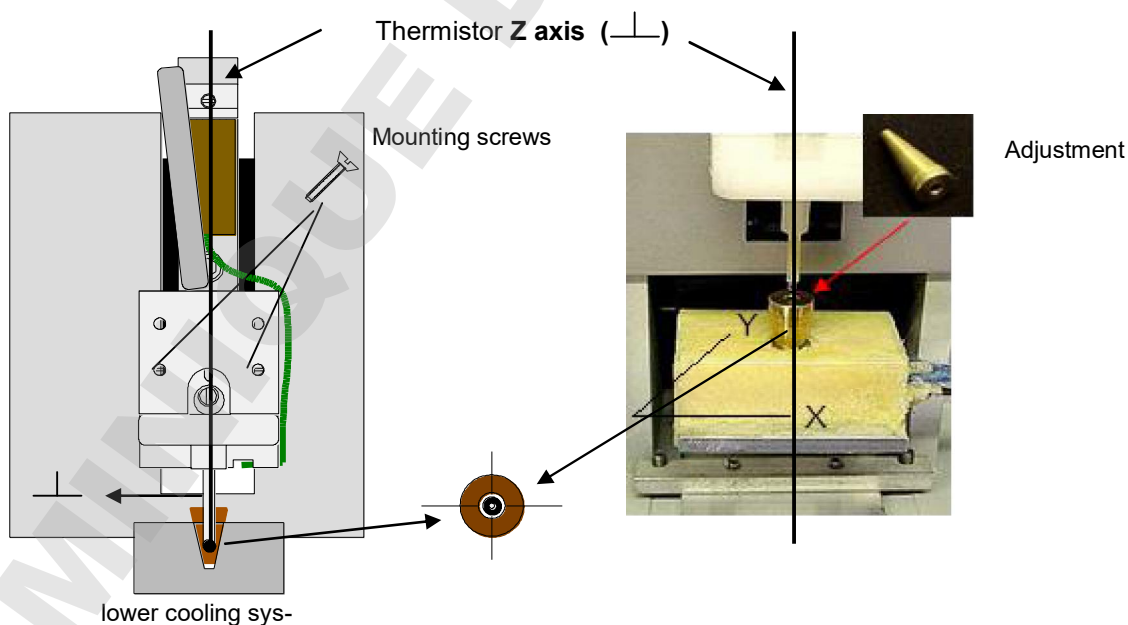


Fig. 97: Thermistor probe Z axis

Fig. 98: Thermistor probe XY axis

Install elevator cover



Fig. 99: Elevator cover with correct cable routing

- 1 Cable
- 2 Cable guide on thermistor probe

- ✓ Correct cable routing
- ✗ Incorrect cable routing

20.



NOTE!
Risk of cable break!

Place cable (fig. 99/1) on thermistor probe in cable guide (fig. 99/2) and install elevator cover on device.



Fig. 100: Remove mounting screws

21. Bolt elevator cover to elevator using the 2 mounting screws (fig. 100/1).

⇒ The thermistor probe is now installed.

Clean cooling nipple

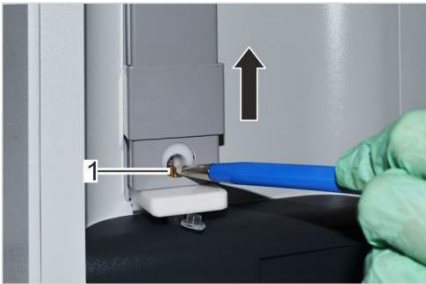


Fig. 101: Clean cooling nipple

22. Clean cooling nipple (fig. 101/1) using a fiberglass pin. For this purpose, move elevator cover up.
23. Power up device on rear side using on/off switch.
24. Calibrate the new thermistor probe.
For this purpose, open the *Replace Probe* menu (*Start menu* → *Settings* → *Lab Options* → *Replace Probe*).

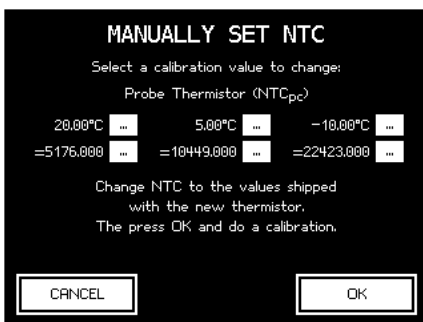


Fig. 102: Calibrate thermistor probe

25. Copy the values from the included data sheet to the fields and tap "OK".
⇒ The system starts the device calibration.
Calibrate the device (🔗 page 56).

8.4.3 Replace fine-wire fuses

Safety gear: ■ Disposable lab gloves

Materials: ■ Flat blade screwdriver
 ■ Fine-wire fuses (1A)



DANGER!
 Risk of death due to electrical current!

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Open cover (fig. 103/1) using a flat blade screwdriver.
3. Remove fine-wire fuse attachment.



Fig. 103: Open fine-wire fuse cover

4. Remove fine-wire fuses (fig. 104/1) from attachment.

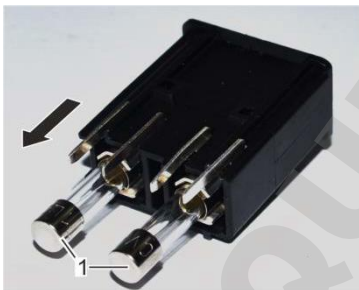


Fig. 104: Remove fine-wire fuses



NOTE!
 Risk of property damage!

The unit has two-phase protection. Use only the following fuses:

HBC fuses with a switching capacity of 1500A

5. Push the fine-wire fuses included with the delivery into the attachment (fig. 105).

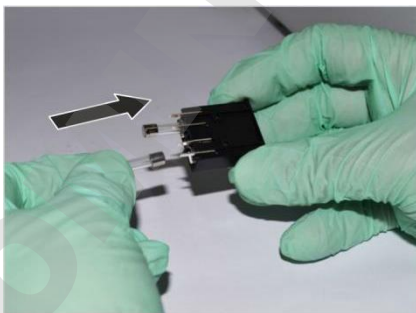


Fig. 105: Install fine-wire fuses

8.4.4 Clean cooling clamp

Personnel: ■ Service technician

Safety gear: ■ Disposable lab gloves

Materials: ■ Fine sandpaper

1. Power down device on rear side using on/off switch.
2. Remove device front panel (☞ on page 89).
3. Clean cooling clamp (fig. 106/1) on lower cooling system using sandpaper.
4. Install device front panel (☞ on page 93).



Fig. 106: Clean cooling clamp

8.4.5 Replace printer paper (Option D only)

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Materials: ■ 1 Paper roll

1. Power down device on rear side using on/off switch.



Fig. 107: Printer (pulled out)

- 1 Paper roll
- 2 Ribbon



Fig. 108: Pull out printer

2. Pull out printer (fig. 108/1).



Fig. 109: Turn knurled screw

3. Turn knurled screw (fig. 109/1) counter-clockwise.
4. Remove empty paper roll from holder and dispose.

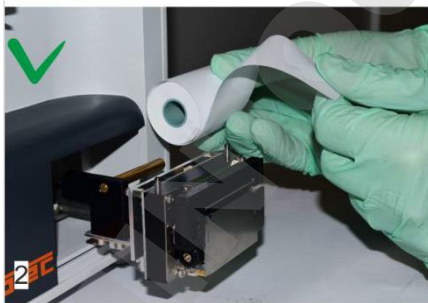


Fig. 110: Install paper roll

5. Cut off beginning of new paper roll (fig. 110/1) and push onto holder.
Pay attention to correct feed direction of paper (fig. 110/2).
6. Position knurled screw (fig. 109/1) and tighten by turning clockwise.
7. Power up device on rear side using on/off switch.



Fig. 111: Activate paper feed

8. On the Start menu, select *Settings* → *Printer*. Tap "*Paper Feed*".



Fig. 112: Paper feed

The paper feed of the printer is activated briefly. (Fig. 112). Tap "*Quit*" to exit the menu.

9. Replace printer cover and push printer into casing.

8.4.6 Replace printer ribbon (Option D only)

- Personnel: ■ User
- Safety gear: ■ Disposable lab gloves
- Materials: ■ 1 Ribbon



Fig. 113: Printer (pulled out)

- 1 Paper roll
- 2 Ribbon

1. Power down device on rear side using on/off switch.



Fig. 114: Pull out printer

2. Pull out printer (fig. 114/1).



Fig. 115: Remove printer cover

3. Remove printer cover (fig. 115/1).

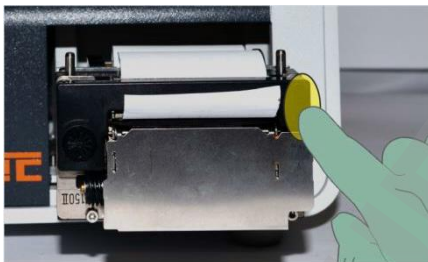


Fig. 116: Push out ribbon

4. Push on Push marking on front side of ribbon (fig. 116).
⇒ The ribbon is released.
5. Remove the released ribbon.

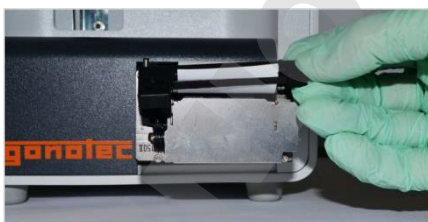


Fig. 117: Feed printer paper

6. Feed printer paper through ribbon (fig. 117).
7. Press ribbon onto device.
⇒ The ribbon snaps into place.
8. Tighten ribbon by turning knob clockwise.
9. Replace printer cover and push printer into casing.

9 Servicing

9.1 Safety notices

Electrical current

**DANGER!****Risk of death due to electrical current on device!**

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately switch off the voltage supply and schedule a repair.
- Always route the power cord so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Ensure easy access to the power socket at all times.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

Risk of infection

**WARNING!****Risk of infection due to sample residue and in case of inadequate hygiene, disinfectant cleaning, and sterilization procedures!**

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfectant cleaning, and sterilization.

We recommend using detergents such as Mikrozyd® AF Liquid, Bacillol® plus 3%, or Korsolex® plus 4% commonly found in clinical-chemical labs to clean and decontaminate the device.

9.1 Service table

The following sections describe the service activities required to ensure device operation under optimum, error-free conditions.

If regular checks show excess wear, shorten the required service intervals based on actual signs of wear. If you have questions regarding service activities and intervals, contact the manufacturer (for contact information, see page 2).

Interval	Service activity	Personnel
monthly	Check elevator support for ease of movement and lubricate if necessary ↳ <i>chapter 9.3 "Lubricate elevator" on page 94</i>	User
	Perform visual inspection of device ↳ <i>chapter 9.4 "Perform visual inspection of device" on page 96</i>	User
	Check reproducibility of measurements ↳ <i>chapter 9.5.1 on page 97</i>	Lab supervisor

9.2 Preliminary steps

Remove device front panel

Personnel: ■ Service technician

Safety gear: ■ Disposable lab gloves

Materials: ■ Allen key SW 2

1. Power down device on rear side using on/off switch.



Fig. 118: Position measuring vessel

2. To protect thermistor, cover thermistor probe with a measuring vessel (fig. 118/1). The cover of the measuring vessel must point forward.

**NOTE!**

Risk of thermistor damage due to loose position of measuring vessel!

Resistance is felt when sliding on measuring vessel. When the measuring vessel clicks into place, it is securely positioned on the thermistor probe.



Fig. 119: Move elevator down

3. Move elevator (fig. 119/1) down.



Fig. 120: Move elevator cover up

4. Move elevator cover (fig. 120/1) up.



Fig. 121: Remove mounting screws

5. Remove the 2 mounting screws (fig. 121/1) using Allen key (SW 2).



Fig. 122: Remove elevator cover

6. Remove complete elevator cover (fig. 122/1).



Fig. 123: Pull out printer

7. Pull out printer (fig. 123/1) from device.

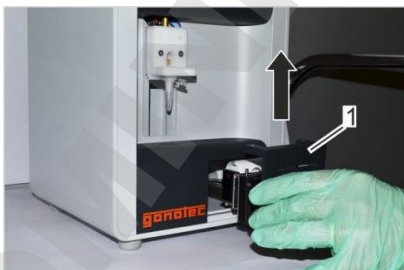


Fig. 124: Remove printer cover

8. Remove printer cover (fig. 124/1) by pulling up.
9. Push printer back into device.

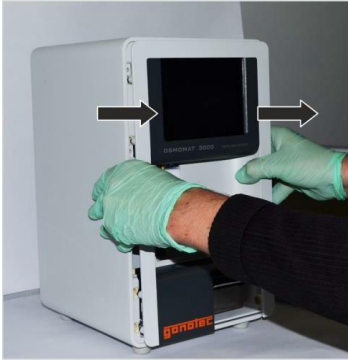


Fig. 125: Remove device front panel

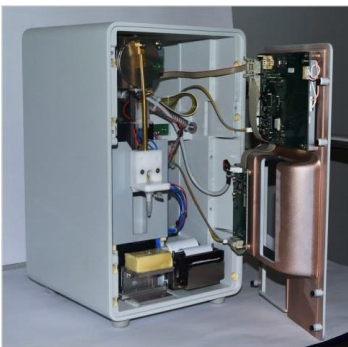


Fig. 126: Device front panel open

10. Remove device front panel by pulling forward (fig. 125). The device front panel is secured to the housing by magnets.



NOTE!

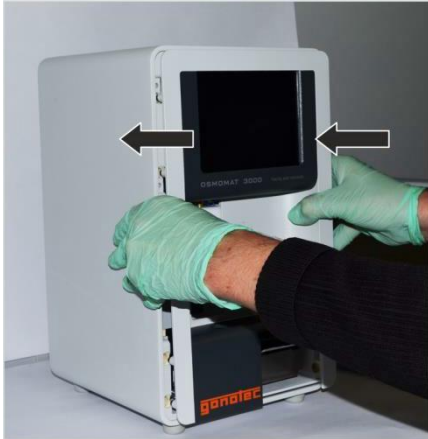
Risk of damage to cables and connectors!

11. Carefully place device front panel on its right side (fig. 126).

⇒ The device front panel is now removed.

Install device front panel

- Personnel: ■ Service technician
 Safety gear: ■ Disposable lab gloves
 Materials: ■ Allen key SW 2



1. Install device front panel on device and push into place (fig. 127).
2. Pull out printer from device using handle.
3. Install printer cover on printer and push down.
 ⇒ The printer cover is now secured.
4. Push printer back into device.

Fig. 127: Install device front panel



Fig. 128: Elevator cover with correct cable routing

- 1 Cable
- 2 Cable guide on thermistor probe

- ✓ Correct cable routing
 ✗ Incorrect cable routing

5.



NOTE!
Risk of cable break!

Route cables on thermistor probe through cable guide (fig. 128/2) and install elevator cover on device.

Pay attention to correct cable routing.



Fig. 129: Tighten mounting screws

6. Bolt elevator cover to elevator using the 2 mounting screws (fig. 129/1).

⇒ The device front panel is now installed.

9.3 Lubricate elevator

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Materials: ■ Silicone spray



NOTE!

Risk of property damage due to wrong lubricant!

The use of lubricating grease can damage the elevator guide.

- Only use silicone spray as lubricant.

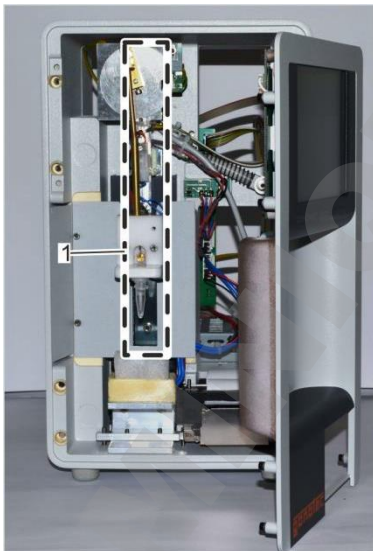


Fig. 130: Location of elevator guide

1. Power down device on rear side using on/off switch.
2. Remove device front panel (☞ on page 89).

Lubricate elevator guide

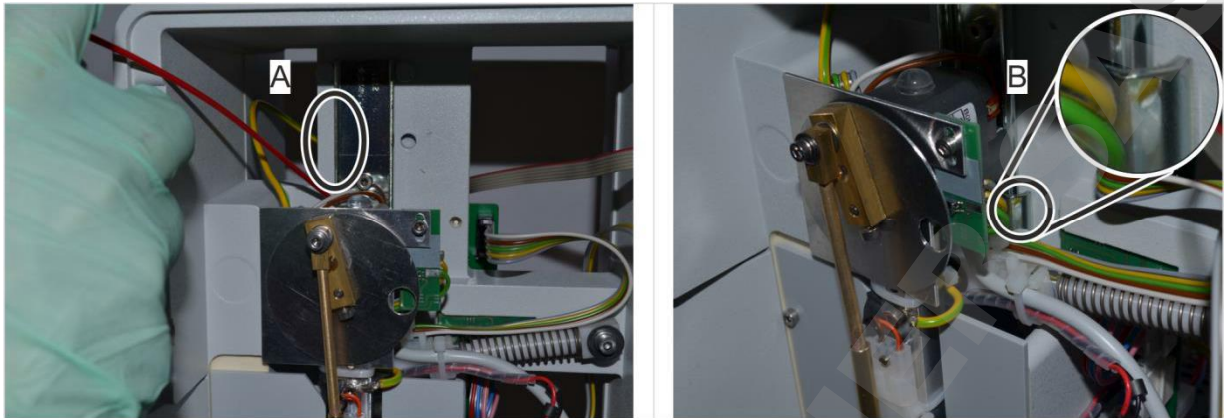


Fig. 131: Lubricate elevator guide

3. Lubricate elevator guide on left (fig. 131/A) and right side (fig. 131/B) of ball bearing using silicone spray.



Tip

The left ball bearing of the elevator guide is not easily accessible.

Therefore, lubricate the upper section (fig. 131/A) on the left side of the elevator guide and move the elevator up and down multiple times.

4. Install device front panel (↪ on page 93).

9.4 Perform visual inspection of device

- Personnel: ■ User
- Safety gear: ■ Disposable lab gloves
- Materials: ■ Fiberglass pin
■ Soft cloth
■ Tweezers

1. Verify that the cables at the rear side of the device are secure and none of them are broken.

In case of cable breaks, replace the cable.

2. Check if foreign objects, such as measuring vessels, are located in the openings of the device (fig. 132/1+2).

Remove any foreign objects using tweezers.



Fig. 132: Inspect device for foreign objects

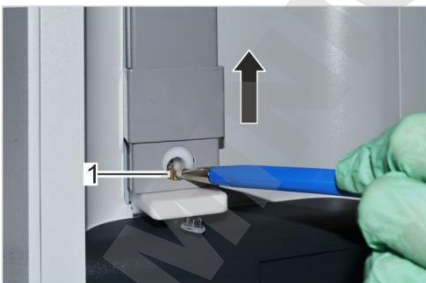


Fig. 133: Clean cooling nipple

3. Clean cooling nipple (fig. 133/1) using fiberglass pin. For this purpose, move elevator cover up.

4. Wipe off dirt and dust from housing using a soft cloth.

9.5 Check reproducibility of measurements

The purpose of the measurement check is to verify the specified performance limits of the device.

9.5.1 Sample test protocol measurement check

Measurement check: Calibration/verification

	ZERO	CAL1	CAL2	REF1	REF2
CAL / mOsmol/kg	Pure water
Sample / mOsmol/kg					
Sample 1
Sample 2
Sample 3
Sample 4
Sample 5
Sample 6
Sample 7
Sample 8
Sample 9
Sample 10
Statistics					
Mean value
Variation
Expected value

Expected value met?
(yes/no)

Is the osmolality within limits? yes no

Thermistor no. Responsible:(Name)(Date)

Note:

Fig. 134: Sample test protocol measurement check



Reproducibility:

- ≤ +/- 2 digits in the measurement range [0..400] mOsmol/kg
- ≤ +/- 0.5% in the measurement range [400..1500] mOsmol/kg
- ≤ +/- 1.0% starting with 1500 mOsmol/kg

10 Disposal

After its useful life, the device must be disposed of under environmentally conscious considerations.

Separation of consumables



WARNING!

Risk of death due to exposure to biohazards!

Improper disposal causes a risk of exposure to biohazards. The resulting risk of infection can lead to serious illness including death.

- Dispose of disposable accessories and other contaminated products according to the requirements for the disposal of biohazards.

Scrapping of device



NOTE!

Harm to environment due to improper disposal!

Electronic scrap and electronics assemblies are to be treated as hazardous waste and can cause harm to the environment in case of improper disposal.

- Always task certified specialist firms with the disposal of the device.

For scrapping, clean device and observe applicable work safety and environmental regulations for disposal.



- Power down device and disconnect power plug.
- Return the device to the manufacturer or a certified disposal firm. Do not dispose of the device through municipal waste.
- Immediately before returning the medical product to the manufacturer, make sure that the device meets strict hygienic conditions. If necessary, disinfect device.

11 Specifications

11.1 Dimensions

Specification	Value	Unit
Weight	6.5	kg
Width	205	mm
Depth	220	mm
Height	360	mm

11.2 Performance parameters

Analytic sensitivity and specificity

Specification	Value	Unit
Measuring range	[0... 3000]	mOsmol/kg
Resolution (across entire measuring range)	1	mOsmol/kg
Measurement display	4.5	digits

Reproducibility

Specification	Value	Unit
Reproducibility	$\leq \pm 2$ digits [0..400]	mOsmol/kg
	$\leq \pm 0.5\%$ digits [400..1500]	mOsmol/kg
	$\leq \pm 1.0\%$ [1500..]	mOsmol/kg

11.3 Operating conditions

Environment

Specification	Value	Unit
Temperature range	10-35	°C
Relative humidity	10–90 (non-condensing)	%
Maximal operating altitude	2000	m

Useful life

Specification	Value	Unit
---------------	-------	------

Specifications

Useful life	10	Years
-------------	----	-------

11.4 Calibration standard

Calibration standard 300 mOs-
mol/kg

Composition	Value
Sodium chloride	9.463 kg
Water (for injection purposes as bulk)	ad 1000 l

Properties

Specifications	Value
Container	Clear glass OPC ampoules
Poison class	F
Water hazard class	1
Disposal	According to good lab practice (GLP)/national regulations

Storage and shelf life

Specifications	Value
Storage class	10 – 13
Temperature range	5°C – 45°C
Stability (at 22°C ambient temperature)	0.5 hours
Shelf life	Listed on packaging

11.5 Connection ratings

Electrical

Specification	Value	Unit
---------------	-------	------

Specifications

Power cord	Detachable power supply cable	
Power connection	100-240	VAC
Frequency	50-60	Hz
Power consumption, max.	80	VA
Fuse (HBC 1500A)	T 1.0	A
Memory Backup (UL: MH 13654 (N))	10 years useful life	
Protection class	IP21	
Protection type	I	
Degree of contamination	2	

Interfaces

Specification	Value
Serial port	2 x RS232 (one RS232 reserved for barcode reader) 1 x USB

11.6 Options
Printer (D)

Specification	Value
Printer	Alphanumeric dot matrix printer, 5x7 matrix, date, time and sample information on each measurement
Number of digits	16 characters per row
Paper	Normal paper, 43mm wide
Print modes	single print, batch printing
	Error message in plain text

Barcode (BC)

Specification	Value
Barcode reader	

11.7 Nameplate

gonotec		CE	<small>Gonotec GmbH Görsch-Heiße-Reichlinstr. 10-11 10555 Berlin, Germany</small>
REF	OSMOMAT 3000 - D	IVD	
SN	13 01 01	i	
⚠	Input V~: 100-240V - 50-60Hz - 45VA — T1.0A Slow Lag	IP 21	
Disconnect Power Before Opening Fuse!		Made in Germany	♻

The nameplate is located at the rear of the device.

Fig. 135: Nameplate

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Appendix

Returning the device

When returning the device for repairs or a refund, please note the following.

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Call or write to request a **free** return order for equipment that is being returned for warranty repair or credit.

You may also request a return order for equipment that is being returned for **non-warranty** repair, but you will be **liable for the cost** of the return order.

3. Clean and disinfect the equipment before returning it to us.



We will charge a processing fee for cleaning and disinfecting contaminated equipment.

Equipment that is strongly contaminated will not be processed by us and will be returned at the customer's expense.



Fig. 136: Position measuring vessel

4. Position a measuring vessel (Fig. 137/1) on the thermistor probe.



The measuring vessel is securely attached to the thermistor probe when it clicks into place.

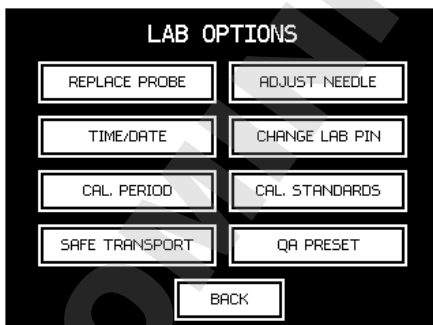


Fig. 137: "Lab Option" menu

5. Move initiation needle to transport position.

Open the menu for configuring the lab options.

In the Start menu, tap

Settings → **Lab Options** → **Safe Transport**.



The menu may be protected with a lab supervisor password.



Fig. 138: "Safe Transport" menu



Fig. 139: Position transport safety device

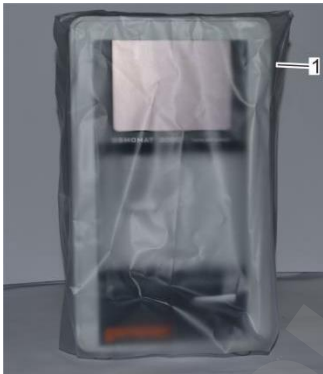


Fig. 140: Device with protective sleeve

6. Tap *Park Needle*.

Tap *Quit* to exit the menu.



WARNING!

Risk of infection from sample residue!

The initiation needle is immersed into the sample during measurements. Contact with the initiation needle increases the risk of infection.

- Wear lab gloves during any kind of work.

7. Tilt transport safety device for thermistor probe and carefully slide behind the thermistor probe (Fig. 139).

8. Pull protective sleeve

(Fig. 140/1) included with the delivery over device.

9. Enclose written information explaining the reason for returning the equipment.

10. If the equipment is being returned for credit, you must include all accessories (power cord, data transfer cable, software disks, manuals, etc.).

11. Return the equipment in its original packaging. If you no longer have the original packaging, you may purchase replacement packaging from Gonotec.

12. Do you have a high sample volume and/or cannot afford downtime?



During repairs, we will provide you with a temporary unit at no cost. Transport costs are only incurred outside the warranty period

Appendix

Limited Warranty

Gonotec product	Duration of Limited Warranty
Software	90 days
Thermistor probe	180 days
Osmometer	2 years

A. Extension of the Limited Warranty

1. Gonotec guarantees the end user that Gonotec products shall be free from manufacturing and material defects for the above periods of validity from the purchase date. The end user must provide proof of the purchase date.
2. For software products, Gonotec's limited warranty applies only to the non-execution of programming instructions. Gonotec does not guarantee that the operation of a product will proceed without errors or interruptions.
3. Gonotec's limited warranty applies only to defects that arise during normal operation of the product. It does not apply under the following conditions:
 - a. Inadequate servicing or improper modification;
 - b. Use of software, interfaces, print media or accessories not supported or supplied by Gonotec; or
 - c. Use of the equipment in a manner not covered by the product specifications.
4. For Gonotec osmometers, the use of measuring vessels of manufacturers other than those of the measuring vessels supplied by Gonotec does not void the customer's warranty claims or any customer support contracts between Gonotec and the customer. If, however, the use of measuring vessels from third-party providers or the cleaning of recycled measuring vessels results in malfunctions or damage to the osmometer or thermistor probe, Gonotec shall assess the normal fees for the time and material required to repair such malfunctions or damage.
5. If Gonotec is notified within the warranty period of a defect in a software product, in media or in a thermistor probe and if the Gonotec warranty applies to the defect, Gonotec shall replace the defective product. If Gonotec is notified within the warranty period of a defect in a hardware product and if the Gonotec warranty applies to the defect, Gonotec shall repair or replace the defective product at its discretion.
6. If Gonotec is unable to repair or replace a defective product to which the Gonotec warranty applies, Gonotec shall refund the purchase price of the product within a reasonable period following notification of the respective defect.
7. Gonotec is not obligated to repair or replace a product or refund its purchase price until the customer returns the defective product to Gonotec.
8. Replacement products may be new or almost new, as long as their functionality is at least that of the replaced product.
9. The Gonotec limited warranty is applicable in all countries in which Gonotec sells the applicable product. The following countries and regions are exceptions: All countries outside the EU. In these countries, the warranty is only valid in the country in which the product was purchased. Contracts for additional warranty services, such as on-site service, may be available from an authorized Gonotec sales partner.

B. Limitation of the Warranty

1. TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL ASSUME ANY ADDITIONAL WARRANTY SERVICES OR ACCEPT ANY OTHER CONDITIONS, EXPRESS OR IMPLIED, WITH REGARD TO THE GONOTEC PRODUCTS.

C. Limitations of Liability

1. To the extent permissible under the applicable local laws, the legal remedies named here shall be the sole and exclusive legal remedies available to the customer.
2. TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS AND WITH THE EXCEPTION OF THE OBLIGATIONS EXPRESSLY NAMED HERE, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL BE LIABLE FOR DIRECT OR INDIRECT, SPECIFIC, INCIDENTAL OR CONSEQUENTIAL LOSSES, WHETHER BASED ON A CONTRACT, A TORTIOUS ACT OR ANOTHER LEGAL THEORY, AND NOTWITHSTANDING PRIOR NOTIFICATION OF THE POSSIBILITY OF SUCH A LOSS.

Respective Jurisdiction

1. This warranty statement guarantees the customer certain legal claims. The customer may have other legal claims that go beyond those outlined here. Such claims vary by state in the US, by province in Canada and by nation elsewhere in the world.
2. Elements of this warranty statement that conflict with local laws can be regarded as amended to comply with the applicable laws. For this reason, certain warranty exclusions and restrictions outlined here may be of no relevance to the customer. In some states of the US, in some Canadian provinces and in some countries outside North America, for example, the following national laws apply:
 - d. Exclusion of the fact that the warranty exclusions and restrictions named here restrict the legal rights of a customer (for example: Great Britain)
 - e. Restriction of the possibilities for manufacturers to enforce such warranty exclusions and restrictions
 - f. Granting of additional warranty claims for the customer, fixing of the validity period for implied warranty services that the manufacturer may not exclude, or non-admission of restrictions relating to the validity period for implied warranty services
3. THE FOLLOWING APPLIES TO CONSUMER TRANSACTIONS IN AUSTRALIA AND NEW ZEALAND: THE CONDITIONS OF THIS WARRANTY STATEMENT NEITHER EXCLUDE LEGAL RIGHTS APPLICABLE TO THE SALE OF GONOTEC PRODUCTS TO SUCH CUSTOMERS NOR REPRESENT A RESTRICTION OR AMENDMENT OF SUCH RIGHTS, BUT INSTEAD REPRESENT A SUPPLEMENT TO THESE RIGHTS, EXCEPT TO THE EXTENT PERMISSIBLE UNDER THE LAW.

Classification of the IVD

The OSMOMAT[®] 3000 cryoscopic osmometer manufactured by Gonotec is a non-invasive in-vitro diagnostic product according to EEC Directive 93/42 (Medical Devices Law). The Osmomat[®] 3000 cryoscopic osmometer is not named in Annex II, list A or B, of the Directive 98/79/EEC for in-vitro diagnostics. Compliance is declared per Annex III. Number 6 of Annex II is disregarded, since the unit's intended use does not include personal use.

EC Compliance Statement—OSMOMAT[®] 3000

Gonotec GmbH
GSG-Hof Reuchlinstr. 10-11
10553 Berlin / GERMANY

We hereby declare that the OSMOMAT[®] 3000 cryoscopic osmometer and its options comply with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the unit acknowledges this.

Date: 2/1/2013

Signature of managing director:

Provisions of Certification

CE compliance requires that the unit is installed and operated in the manner described in this manual. Any departure from the specifications or independent modifications of the unit without the express consent of Gonotec GmbH may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

Appendix

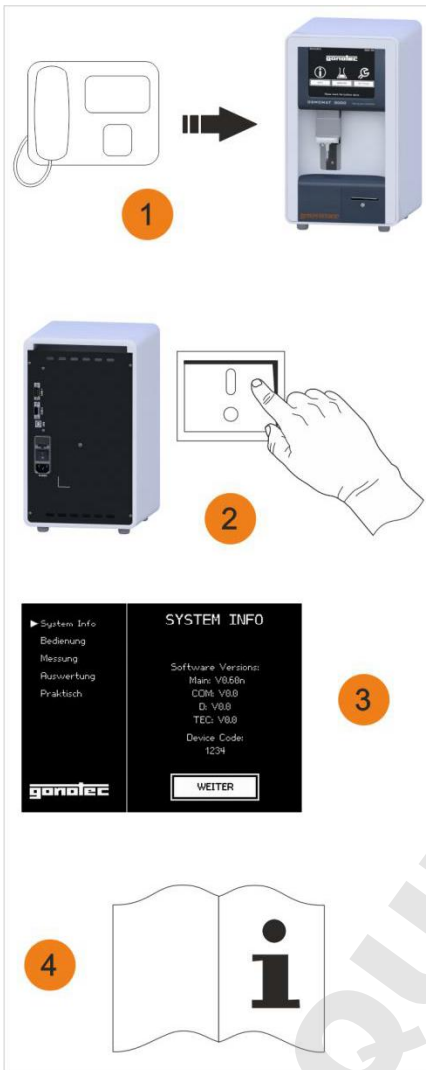
Consumables

Item no.	Item	Pc. / VE
9/30/0010	Measuring vessel for OSMOMAT 3000	1,000
9/30/0020	Calibration standard 300 mOsmol/kg (ampoules of 1ml each)	10
9/30/0100	Calibration standard 100 mOsmol/kg (ampoules of 1ml each)	10
9/30/0290	Reference solution OSMOREF® 290 mOsmol/kg (ampoules of 1ml each)	10
9/30/0500	Calibration standard 500 mOsmol/kg (ampoules of 1ml each)	10
9/30/0850	Calibration standard 850 mOsmol/kg (ampoules of 1ml each)	10
9/30/2000	Calibration standard 2000 mOsmol/kg (ampoules of 1ml each)	10
9/30/1010	Printer paper roll for OSMOMAT 3000-D	8
9/30/1020	Continuous loop ribbon cartridge for OSMOMAT 3000-D	1

Accessories and Replacement Parts

Item no.	Item	Pc. / VE
32.3.0010	Thermistor probe for OSMOMAT 3000 (50µl sample volume)	1
32.3.2010	Thermistor probe for OSMOMAT 3000-M (15µl sample volume)	1
9/30/0030	Blow-out device	10
6/30/0020	Initiation needle	1
9/20/0165	Data cable for RS 232 interface OSMOMAT 3000	1
9/20/0166	USB cable	1
30.2.0030	Adjustment tool	1
9/20/0100	Power cord, 2 meters	1
00.9.0106	Package with fine-wire fuses, 1,0 A Lag, 230V	10

Before Calling Gonotec



- 1 Use a telephone located close to the device.
- 2 Power up device.



NOTE!

Danger in case of continuous acoustic alarm!

In case of continuous acoustic alarm, the electronics components of the device can be damaged.

- Power down device again.

- 3 Note down the serial number of the device. To find the serial number, select *Start menu* → *Info*.
- 4 Have the device documentation available.

Contact info:

Gonotec GmbH
 GSG-Hof Reuchlinstr.10-11
 D-10553 Berlin

Phone: (030) 7809 588-0
 Fax: (030) 7809 588-88
 E-mail: contact@gonotec.com
 Web: <http://www.gonotec.com>

Fig. 141: Contact Gonotec